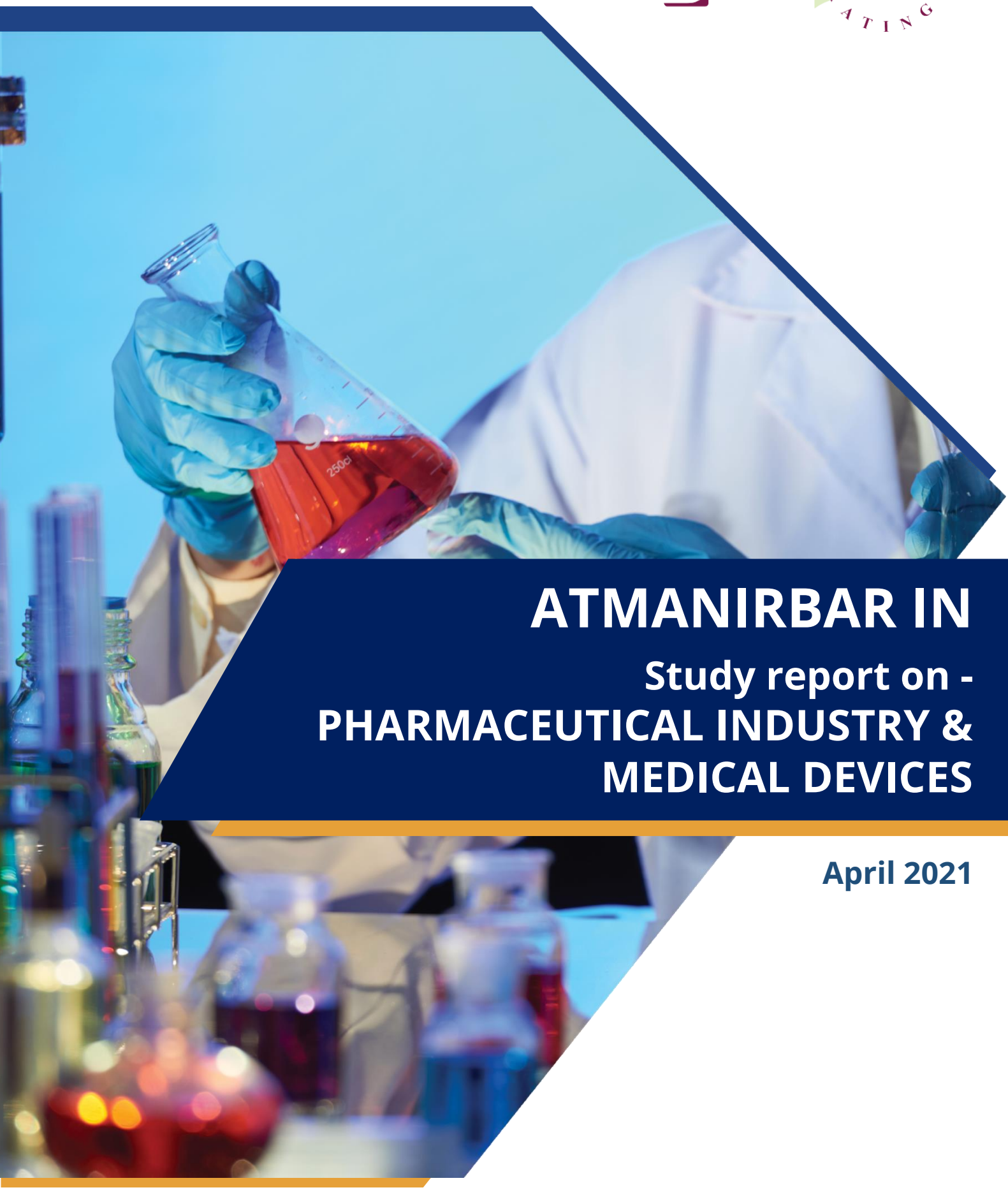

ATMANIRBAR IN

Study report on - PHARMACEUTICAL INDUSTRY & MEDICAL DEVICES

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Introduction

'Atmanirbharata' (Self-sufficient in Hindi) is an attractive catchword. In fact, for almost half a century post-independence, India has been talking of self-sufficiency – in food, industrial inputs, key scientific and defence areas, etc. Given the foreign exchange position of India, the amount of money available for imports was anyway very limited. However, the policy makers were also aware of the limitations of such a policy, particularly in certain sophisticated technological fields. Later, in the 90s, as multilateralism became the mantra of a globalised world, India also had to make choices. With a gradual increase in the Forex kitty, thanks to increasing exports, software prowess post the Y2K phenomenon and large inflow of remittances by Indian diaspora, imports got liberalised. The flood-gates for the import of cheaper goods, particularly in certain fields like bulk drugs and consumer electronics, got opened. It is only in the context of Chinese aggression against India in the last couple of years that the policy makers have once again taken stock of the situation and started talking of 'Atmanirbharata'.

China has been a difficult country to deal with to most democracies in the world. It has problems with USA, Canada, Western Europe, Japan, India, ASEAN countries and Australia. As it has become the world's manufacturing hub for a large number of items, the second largest economy, as also one of most powerful armies of the world, China is rewriting the rules of the game. In the context of the Covid pandemic, which started in China, and the disruptions caused, all countries are realising the perils of 'concentration risk', and India is no exception. India has the advantages of a large domestic market, favourable demographic position, cheaper labour and a supportive infrastructure in terms of investment and finance, and hence, is definitely in a position to increase its own manufacturing base and be reasonably self-sufficient in most areas. The Government of India's policies are aimed at facilitating this.

Brickwork Research Team has come out with two Study Reports – one on Bulk Drugs and Medical Devices, and another on Telecom, and hopes readers find these interesting. Readers' comments are welcome.

Vivek Kulkarni IAS (Retd)
Managing Director

OVERVIEW

India is a leading player in the global generics market, with a 20% share in supplies by volume, and a strong network of 10,500+ manufacturing units and 3,000 pharma companies. Of these pharma companies, more than 2,000 are WHO-GMP approved plants and 253 are European Directorate of Quality Medicines (EDQM) approved plants, all with modern state-of-the-art technology.

Besides, the sector also has the largest number of US-FDA-compliant Pharma Plants (more than 262 including Active Pharmaceutical Ingredients (APIs)) outside India.

India ranks third worldwide for production by volume and 14th by value. The Indian pharmaceutical sector fulfils over 62% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK. Presently, over 80% of the antiretroviral drugs used globally to combat Acquired Immune Deficiency Syndrome (AIDS) are supplied by Indian pharmaceutical firms.

India manufactures around 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different APIs. The API industry is ranked the third largest in the world, contributing 57% of APIs to the prequalified list of the WHO.

The Indian pharmaceutical market is currently valued at about $ 41 billion, wherein pharmaceutical exports from India stood at US$ 20.70 billion in FY 20, which is equally contributed by the domestic pharmaceutical market of about $ 20.30 billion. Indian drugs are exported to more than 200 countries in the world, with the US being the key market. Generic drugs account for 20% of the global export in terms of volume, making the country the largest provider of generic medicines globally. It is expected to expand even further in the coming years. As of October 2020, India exported pharmaceuticals worth US$ 13.87 billion in FY21.

Although bulk drug exports have a higher volume, in terms of value, APIs and drug formulation contribute 80% of the total exports.

World	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
Bulk drugs	2,18,209	2,17,920	2,35,332	2,26,833	2,28,236	2,73,463	2,75,329
Drug formulations	6,45,571	6,85,578	8,27,604	8,49,349	8,32,140	10,06,816	11,30,037
Surgicals	18,285	18,308	19,847	22,353	24,317	27,856	31,813
Total (Rs.mn)	8,82,064	9,21,805	10,82,783	10,98,535	10,84,692	13,08,136	14,37,179

Source: **CMIE Industry outlook**

Overview of Bulk drug

A bulk drug, also called an API, is the chemical molecule in a pharmaceutical product (medicines we buy from the chemist) that lends the product the claimed therapeutic effect.

API is also defined as any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of the body.

The key starting material for the production of an API is the raw material, intermediate or another API.

A drug intermediate is a material produced during intermediate steps in the synthesis of an API that must undergo further molecular change or processing before it becomes an API. The drug manufacturing industry entails the manufacture, extraction, processing, purification and packaging of chemical material to be used as medications.

It can be primarily classified in to two stages:

Primary processing: The production of APIs or bulk drugs from the Key Starting Materials (KSMs) or Drug Intermediaries (DIs)

Secondary processing: The conversion of the API into products suitable for administration

The basic production of bulk drug substances may employ three major types of processes: fermentation, organic chemical synthesis, and biological and natural extraction. These manufacturing operations may be discrete batch, continuous or a combination of these processes.

Antibiotics, steroids and vitamins are produced by fermentation, whereas many other drugs are produced by organic synthesis. Historically, most drug substances were derived from natural sources such as plants, animals, fungi and other organisms. Natural medicines are pharmacologically diverse and difficult to produce commercially due to their complex chemistry and limited potency, and hence, the commercial production of these drugs was done either through fermentation or chemical synthesis.

Bulk Drugs: Dependence on Imports- Reasons and Expected Change

India's pharma import bill is to the tune of $ 61 billion, predominantly comprising bulk drugs to the tune of $32.2 billion. Of the bulk drugs, imports from China alone are to the tune of $23 billion.

It may be noted that imported bulk drugs form about 25% to 30% in domestic formulation exports, and the government is striving to increase the value addition of indigenous goods.

On the import of bulk drugs from China, these imports are used to manufacture key medicines such as Paracetamol, Metformin, Ofloxacin, Metronidazole, Ampicillin and Amoxicillin.

Year	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
Bulk drugs	1,89,911	1,98,332	2,12,260	1.83,725	1,92,911	2,48,501	2,41,718
Drug formulation	89,953	95,609	1,03,596	1,11,440	1,18,698	1,41,257	1,59,674
Surgicals	33,562	34,647	36,346	36,270	37,762	49,426	49,896
Total (Rs. million)	3,13,426	3,28,588	3,52,202	3,31,435	3,49,371	4,39,184	4,51,288

Source: CMIE Industry outlook

Before 1991, India was dependent on China only to the extent of 0.3%. Indian Public Sector Enterprises in the sector, viz., Hindustan Antibiotics Ltd (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL), were catering to bulk drug production; apart from that, other private companies such as Ranbaxy, Aurobindo Pharma and Torrent had tie-ups with multinational majors and were making bulk drugs, which met the entire domestic requirement.

During the time, China stepped into huge bulk drug manufacturing in a big way. The country had close to 7,000 bulk drug parks, which provided all the infrastructure, viz., land, building, common effluent treatment plants, subsidised power and water, for multinationals to set-up, which eventually lowered the production costs of these bulk drugs.

As these bulk drugs are available at cheaper rates, Indian formulation companies resorted to huge imports, thus rendering bulk drug manufacturing unviable, which ultimately led to the closure of HAL and IDPL, among others, in India.

China's increased competitiveness vs India's challenges

China's strength	India's weakness
Ease of doing business	Inadequate infrastructure
Fast track approvals	No single window for approvals
Environmental Flexibility	Longer timeline for environmental clearances
Cheaper land and power	High manpower cost and power cost.
Regulatory approvals on prompt basis	Complex regulatory structure
Refund of duty drawback	Price volatility due to high import dependency

Earlier scheme in 2015: The government declared 2015 the 'Year of API'. However, the scheme remained on paper and was not implemented.

Current Atmanirbar: In the wake of Covid-19 and the underlying tension with China, India has realised it is critically dependent on China in the bulk drug segment, importing almost 69% of its requirement). This was understood by the pharma sector in the supply chain disruptions of KSM /API caused because of Covid-induced quarantine imposed by various provinces in China. Furthermore, if the border tension also intensifies, India's competitiveness in the formulation segment shall remain questionable.

ATMANIRBAR PACKAGE FOR PHARMA SECTOR

The Government of India has recognised that future growth in the pharmaceutical sector is contingent upon our ability to ensure uninterrupted supply of quality bulk drugs and also our capacity to upscale their manufacturing to meet emergency requirements. An intervention is required so that India becomes the pharmacy of the world in the true sense, for which the government has brought in the following schemes:

Schemes	Purpose	Quantum of incentives (Rs.crore)
PLI for KSM, DI and API	Large-scale domestic manufacturing in 53 identified KSM/DI/API in 41 eligible products	6,940
Bulk drugs Park	Setting-up of infrastructure facilities for three bulk drug parks by state government	3,000

Production-Linked Incentive Scheme for KSM/DI/API

The Government of India has approved a scheme called the Production-Linked Incentive (PLI) Scheme for promoting the domestic manufacture of critical KSMs and DIs / APIs in India (the Scheme), which has been notified vide Gazette Notification no. - 31026/16/2020-Policy, dated - 21 July 2020.

The objective of the Scheme is to attain self-reliance and reduce import dependence in critical KSMs/DIs/APIs. Under the Scheme, financial incentives shall be given based on the threshold investment and domestic sales made by selected applicants for eligible products.

Particulars	Details
Tenure	2020-21 to 2029-30
Total outlay	Rs.6,940 crore

Quantum of incentives	• **For fermentation-based products: Incentives at the rate of 20% for the first four years (2023-24 to 2026-27), 15% for the fifth year (2027-28) and 5% for the sixth year (2028-29) on Net sales** • **For chemically synthesised products: Incentives at the rate of 10% for five years (2022-23 to 2027-28) on Net sales** • **Base year: Financial year 2019-2020**
Eligible product segments and incentives	• **Target 1 Segment - Four fermentation-based KSMs/ drug intermediates- Rs.3,600 crore** • **Target 2 Segment- 10 fermentation-based niche KSMs/drug intermediates/APIs- Rs.1,000 crore** • **Target 3 Segment - Four chemical synthesis-based KSMs/ drug intermediates/ APIs- Rs.960 crore** • **Target 4 Segment- 14 chemical synthesis-based KSMs/ drug intermediates/APIs-Rs.1,380 crore**
Domestic value addition	• **90% in case of fermented based products** • **70% in case of chemical synthesis products**
Minimum committed investment	**Rs.20 to Rs.400 crore depending on product. It should only be a green field project only. Investments include expenditure made on building, R&D, and plant and machinery. Plant and machinery should only be new equipment. Expenditure in land is not included.**
Applicant's eligibility	• **Maximum two to four applicants eligible per products** • **Applicant should be manufacturers of KSM/DI/API and registered in India** • **Should not have been declared bankrupt/wilful defaulter/defaulter/fraud by any bank/FI/NBFC** • **Net-worth of the applicant should not be less than 30% of the proposed investment** • **If the application is received from any Central Public Sector Enterprise (CPSE) under the administrative control of the Department of Pharmaceuticals, subject to the fulfilment of eligibility criteria as specified in the Scheme, such applicant CPSE may be selected in national interest.**

Evaluation criteria	• **The applicants shall have to meet the eligibility criteria of the minimum annual production capacity and threshold investment for each of the eligible products for which approval has been granted under the scheme.** • **In case the committed annual production capacity and corresponding investment committed is more than the minimum annual production capacity and threshold investment, the selected applicant shall have to complete the installation of committed annual production capacity and make committed investment as stated in the approval letter in order to be eligible to claim incentive.** • **Eligibility under the Scheme shall not affect eligibility under any other scheme and vice versa.** • **All eligible applicants shall be ranked on the basis of marks obtained in the evaluation criteria.** • **Evaluation criteria is determined in the terms of Committed Annual production capacity and the quoted sale price of eligible product in the ratio of 35:65** • **The applicant securing the highest marks shall be ranked 1, followed by the applicant securing the second highest marks and so on.** • **The selection of the applicants shall be in the order of their ranks.** • **The number of selected applicants shall be limited by the maximum incentive available for each eligible product.** • **The incentive for a selected applicant committing annual production capacity as a multiple of the minimum annual production capacity may exceed the maximum incentive for each selected applicant and will depend on the ranking of such an applicant, committed capacities of other selected applicants and maximum incentive earmarked against each eligible product.**
Computation of incentive	• **The incentive under the scheme shall be applicable only on the sales of the eligible product to the domestic manufacturers.** • **The annual incentive to be disbursed shall be subject to the ceiling of the annual incentive, as stated in the approval letter.** • **The incentive shall be calculated as follows: Net sales (Domestic) of eligible product * Rate of incentive**

	• Net sales shall be calculated as per the actual sale price or sale price quoted by the applicant in the application form, whichever is lower. • The sale price quoted in the application form shall be the maximum price on which the applicant can claim incentive and shall remain fixed throughout the tenure of the Scheme. However, it is clarified that the price quoted by the applicant is only for the calculation of the incentive, and there is no condition or restriction under these guidelines on the actual sale price of the eligible product.
Other details	• IFCI Ltd has been appointed as the Project Management Agency (PMA). • Applications are scrutinised by the PMA and selected by the empowered committee. • The selected applicant has to furnish a bank guarantee to the tune of 1% on the committed investment. • The disbursement of incentives is done half yearly/annually.

Status so far

- The industry has shown very good response to these schemes, whereby 215 applications made by 83 pharmaceutical manufacturers have been received under the PLI scheme for bulk drugs.
- Key manufacturers who have submitted their applications include Alembic Pharmaceuticals Ltd, Aurobindo Pharma Ltd, Bajaj Healthcare Ltd, Brooks Laboratories Pvt Ltd, Cadila Pharmaceuticals Ltd, Dr Reddy's Laboratories Ltd, Lupin Ltd, IPCA Laboratories Ltd, Sun Pharmaceutical Industries Ltd, Surya Life Sciences Ltd and Vinati Organics Ltd.
- In total, 215 applications have been received for 36 products spread across four target segments.

Government Notification

The government vide five notifications has approved projects worth Rs.5,366 crore under the PLI scheme, which are as follows:

Notification 1: The government vide its press release dated 22 January 2021 has approved the first set of five pharma projects for Target 1 Segment – fermentation-based KSM/DIs, under the PLI scheme, which are as follows:

Sl.No	Name of the approved Applicant	Name of Eligible product	Committed Production capacity (MTs)	Committed Investment (Rs.crore)
1	Aurobindo Pharma Ltd (through Lyfius Pharma Ltd)	Penicillin G	15,000	1,392
2	Karnataka Antibiotics and Chemicals Ltd	7-ACA	1,000	275
3	Aurobindo Pharma Ltd (through Lyfius Pharma Ltd)	7-ACA	2,000	813
4	Aurobindo Pharma Ltd (through Quole Pharma Ltd)	Erythromycin Thiocyanate (TIOC)	1,600	834
5	Kinvan Private Limited	Clavulanic Acid	300	447.17

The setting-up of these plants will lead to a total committed investment of Rs. 3,761 crore by the companies and employment generation for around 3,825 people. The commercial production is projected to commence from 1 April 2023.

The Target Segment-I includes four eligible products, viz., Penicillin G, 7-ACA, Erythromycin Thiocyanate (TIOC) and clavulanic acid, in which the country is presently fully import-dependent; these were considered on priority as per the decided evaluation and selection criteria.

Notification 2: The government vide its press release dated 26 February 2021 has approved eight pharma companies for Target Segment- II (fermentation-based niche KSMs/DIs /APIs) under the PLI scheme, which are as follows:

Sl.No	Name of the approved Applicant	Name of Eligible product	Committed Production capacity (MTs)	Committed Investment (Rs.crore)
1	M/s Natural Biogenex Private Limited	Betamethasone	12	31.43
2	M/s Natural Biogenex Private Limited	Dexamethasone	10	26.19
3	M/s Natural Biogenex Private Limited	Prednisolone	15	39.29
4	M/s Symbiotec Pharmalab Private Limited	Prednisolone	15	5

5	M/s Macleods Pharmaceutical Limited	Rifampicin	200	198.36
6	M/s Optimus Drugs Private Limited	Vitamin B1	200	35.00
7	M/s Sudarshan Pharma Industries Limited	Vitamin B1	200	57.00
8	M/s Optimus Drugs Private Limited	Streptomycin	50	30

Notification 3: In the same press release dated 26 February 2021, the government has approved six companies under Target Segment III (key chemical synthesis based KSMs/DIs)

Sl.No	Name of the approved Applicant	Name of Eligible product	Committed Production capacity (MTs)	Committed Investment (Rs.crore)
1	M/s Saraca Laboratories Limited	1,1 Cyclohexane Diacetic Acid (CDA)	3,000	50
2	M/s Emmennar Pharma Private Limited	1,1 Cyclohexane Diacetic Acid (CDA)	1,500	21.94
3	M/s Hindys Lab Private Limited	1,1 Cyclohexane Diacetic Acid (CDA)	3,000	37.60
4	M/s AartiSpeciality Chemicals Limited	2-Methyl-5Nitro-Imidazole (2-MNI)	4,000	77.87
5	M/s Meghmani LLP	Para amino phenol	13,500	55.06
6	M/s Sadhana Nitro Chem Limited*	Para amino phenol	36,000	197.27

*subject to outcome of writ petition

The setting-up of these plants will lead to total committed investment of Rs.862.01 crore by the companies and employment generation for around 1763 people.

Notification 4: The government vide press release dated 11 March 2021 has approved 14 companies in Target IV Segment (other chemical synthesis based KSMs/ DIs /APIs), which are as follows :

Sl.No	Name of the approved Applicant	Name of Eligible product	Committed Production capacity (MTs)	Committed Investment (Rs.crore)
1	M/s Anasia Lab Private Limited	Meropenem	08	26.12
2	M/s Rajasthan Antibiotics Limited	Meropenem	48	28.25
3	M/s Centrient Pharmaceuticals India Private Limited	Atorvastatin	180	137.74
4	M/s Anasia Lab Private Limited	Olmesartan	75	27.09
5	M/s Andhra Organics Limited	Olmesartan	75	30.50
6	M/s Solana Life Sciences Private Limited	Artesunate	40	20.00
7	M/s RMC Performance Chemicals Private Limited	Aspirin	1500	12.00
8	M/s Surya Remedies Private Limited	Ritnovir	20	20
9	M/s Honour Lab Limited	Lopinavir	49	31.01
10	M/s Hindys Lab Private Limited	Acyclovir	525	30.37
11	M/s Dasami Lab Private Limited	Carbamazepine	260	30.28
12	M/s Dasami Lab Private Limited	Oxcarbazepine	195	25.58
13	M/s Hetero Drugs Limited	Oxcarbazepine	195	19.00
14	M/s Hazelo Lab Private Limited	Vitamin B6	70	21.53

The setting-up of these plants will lead to a total committed investment of Rs.459.47 crore and employment generation for around 3,715 people by the companies. The commercial production of these plants is projected to commence from 1 April 2023 onwards.

Notification 5: The government vide press release dated 13 April 2021 has approved 16 applicants under the PLI scheme under Target Segment IV, (other chemical synthesis based KSMs/ DIs /APIs), which are as follows:

S.No.	Name of the Applicants	Name of Eligible Product	Committed production capacity (in MT)	Committed Investment (Rs. in crore)
1	Honour Lab Limited	Valsartan	300	26.88
2	Anasia Lab Private Limited	Losartan	400	29.12
3	Hetero Drugs Limited	Levofloxacin	230	9
4	Chemex Global	Levofloxacin	115	20
5	Surya Life Sciences Limited	Levofloxacin	230	20
6	Andhra Organics Limited	Sulfadiazine	360	38.7
7	Sreepathi Pharmaceuticals Limited	Ciprofloxacin	900	16.05
8	Sreepathi Pharmaceuticals Limited	Ofloxacin	300	16.05
9	Global Pharma Healthcare Private Limited	Ofloxacin	200	16.49
10	Andhra Organics Limited	Telmisartan	360	40
11	Kreative Actives Private Limited	Diclofenac Sodium	350	20.74
12	Amoli Organics Private Limited	Diclofenac Sodium	175	6.56
13	Vapi Care Pharma Private Limited	Diclofenac Sodium	525	21
14	Honour Lab Limited	Levetiracetam	840	31.36
15	Hetero Drugs Limited	Carbidopa	16	18
16	Hetero Drugs Limited	Levodopa	40	18.75

The setting-up of these plants will lead to a total committed investment of Rs.348.70 crore and employment generation for around 3,042 people by the companies. The commercial production of these plants is projected to commence from 1 April 2023 onward.

Conclusion: With this approval, all the 215 applications received have been considered, and a total of 47 applications (excluding two successful applications withdrawn subsequently) with a committed investment of Rs.5,366.35 crore (investments of two withdrawn applicants excluded) have been approved by the government under the PLI scheme for APIs. The setting-up of these plants will make the country self-reliant to a large extent with respect to these bulk drugs. The disbursal of PLIs by the government over the six-year period would be up to a maximum of around Rs.6,000 crore, against the budgetary outlay of Rs.6,940 crore.

Bulk Drug Parks

A bulk drug park will have a designated contiguous area of land with common infrastructure facilities for the exclusive manufacture of APIs, DIs or KSMs.

The common infrastructure facilities shall include:

- **Central Effluent Treatment Plant(s) (CETP)**
- **Solid waste management**
- **Storm water drains network**
- **Common solvent storage system, solvent recovery and distillation plant**
- **Common warehouse**
- **Dedicated power sub-station and distribution system with necessary transformers at factory gate**
- **Raw, potable and demineralised water**
- **Steam generation and distribution system**
- **Common cooling system and distribution network**
- **Internal road network, compound wall**
- **Common logistics (clearing and forwarding, insurance, transportation, customs, weighbridges, and so on)**
- **Advanced laboratory testing centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers**
- **Emergency response centre**
- **Safety hazardous operations audits centre**
- **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 a track record of such competitive technology development for import substitution**
  - **e) Industry academia linkage centre**
  - **f) Training centre**

These parks are expected to lower the manufacturing costs of bulk drugs in the country and increase competitiveness in the domestic bulk drug industry. The centre's scheme will support three selected parks in the country by providing a one-time grant-in-aid for the creation of common infrastructure facilities. The details of the scheme are as follows:

Particulars	Details
Number of Parks	Maximum of three parks are supported under this scheme
Total financial outlay	Rs. 3,000 crore. Maximum Rs.1,000 crore per park
Grant in Aid	The grant-in-aid will be 70% of the project cost of the Common Infrastructure Facilities (CIF). In the case of North Eastern and hilly states (i.e, Himachal Pradesh, Uttarakhand, the UT of Jammu & Kashmir and the UT of Ladakh), the grant-in-aid will be 90% of the CIF.
Project cost	Cost of setting-up CIF in the park
Preferred products	The preferred products are the APIs/DIs/KSMs for which the country is majorly dependent on imports. Formulations shall not be permitted.
Implementing Agency	A State Implementing Agency (SIA) shall be a legal entity set-up by the state government for the purpose of implementing the Bulk Drug Park Project.

Core benefits of this scheme

One of the biggest costs for a pharma manufacturing facility is for effluent treatment and common utilities, which the government will be effectively able to address through the construction of bulk drug parks, where all these facilities are made available to companies, and therefore, they become cost-competitive. At the same time, as these parks operate the facilities at larger volumes, the utilisation of assets goes up, and therefore, the operating cost to manufacturers comes down.

BWR Standpoint

- The scheme is evolved with the core objective that medicines are critical to mankind, and any disruption in their supply shall have a significant adverse impact on the functionality of the economy, and hence, the government places huge importance on attain self-reliance in the manufacture of critical/ life-saving drugs.

- India's dependence on China is around 69% in the bulk drug segment. These schemes once operationalised are expected to reduce sourcing dependence on China in the bulk drug segment by 25 % (69% to 43%) in the next four to five years.

- In the wake of Covid, not only India, but also other countries are looking at ways to ensure continuous supply of drugs to their citizens. Although it is not possible for all countries to achieve self-sufficiency in indigenous production (due to size and regulatory constraints), they are also

looking at alternate supply arrangements rather than depending only on China, in which case, India becomes a favourable option for most countries.

- Unlike formulations, there are no brand exclusivity/ Intellectual Property Rights (IPR), which may restrict the production of bulk drugs.

- Eligibility under this scheme shall not affect eligibility under other schemes and *vice versa*. For example, if the unit is already enjoying SEZ benefits, IT rebate, duty drawback and so on, the same shall continue to apply in addition to incentives eligible under this scheme.

- The faster implementation of this scheme is possible as it does not require any public acceptance and is not exposed to any political conflict.

- As per government estimates, the scheme is expected to bring in investments to the tune of around Rs.15,000 crore, generate sales of about Rs.2,94,000 crore and incremental exports of about Rs.1,96,000 crore, and create employment options for about 20,000 direct and 80,000 indirect jobs for skilled and unskilled people in the next five years.

No doubt, the Atmanirbar package announced for the pharma sector is definitely a game changer and is poised to make Indian Pharma a $100 billion industry in the near future.

Medical Device Industry

As per the WHO, a medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

India is the fourth largest market for medical devices in Asia and is among the top 20 markets for medical devices in the world. Between 2009-2016, medical devices market has grown at a CAGR of 15.8% and is currently valued at $11 billion. It is expected to reach an estimated $65 billion by 2025.

The Indian medical device industry is highly fragmented and is dominated by MNCs, which occupy around 80% market share. Domestic manufacturing is largely restricted to low-value-add items such consumables and disposables.

Various factors attributed to lower domestic production in medical device industry:

A. **There is a lack of favourable government policies, viz., the absence of single window clearance, lower taxes for manufacturing of critical equipment, tax holidays, earmarked land and subsidised loans.**

B. **Uneven and inefficient distribution of healthcare system- 69% of the population lives in rural areas, whereas 73% of qualified doctors live in urban areas. Only 8% of qualified doctors live in rural areas, and 19% of doctors live in semi- urban areas.**

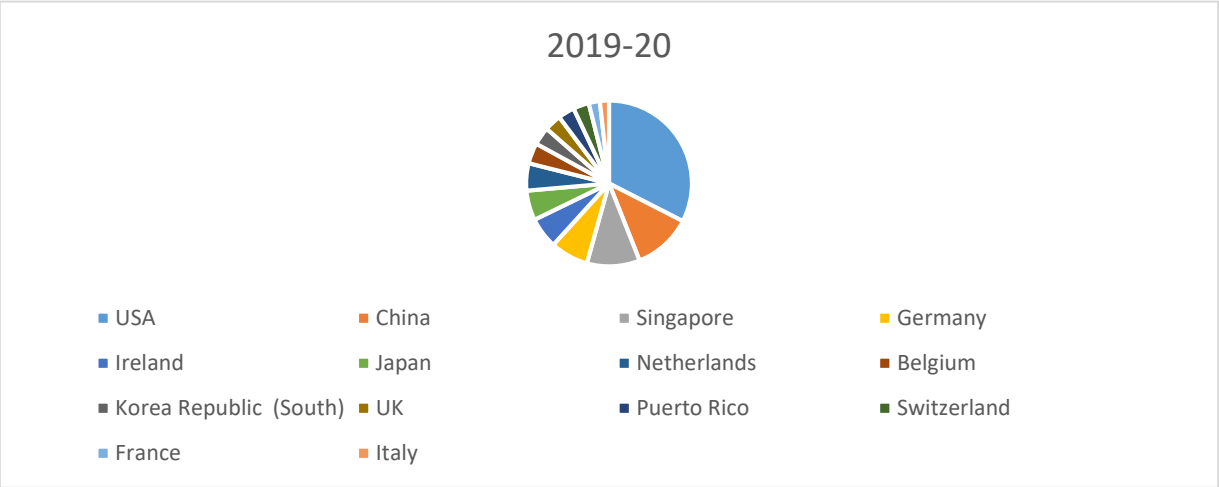
C. **Inadequate infrastructure: Non-alignment with global quality and the lack of quality product testing facilities hinder further progress.**

D. **Availability of doctors and hospital infrastructure: As on 31 March 2019, around 11.59 lakh doctors were registered with the State Medical Council/Medical Council of India, of which, assuming 80% are active, there are only around 9.27 lakh doctors, which gives a doctor:population ratio of 1:1456, which is much lower than the WHO norm of 1: 1000. Similarly, the number of hospital beds in India is around 17.59 lakh (beds in govt hospital- 7.39 lakh, private hospital- 9.73 lakh, charitable institution- 0.47 lakh), which translates to 131 beds per 1,00,000 persons, which is lower than that of many developing countries.**

E. **Medical devices, unlike pharmaceuticals, are dependent on a mix of technologies such as engineering, electronics, material sciences and information technologies. The lack of focus on innovation, technology and capital investments limit the prospects of this sector.**

Reliance on China

- **In 2019-20, India imported medical devices worth ₹42,245 crore, of which China accounted for an 11% share, at ₹4,559 crore. Of the 147 product categories, dependence on China is very high in 11 product categories (acupuncture apparatus, confirmation kits, clinical thermometers, fistula needles, ice bags and so on), which constitutes up to 87 % of imports. However in surgicals, imports from other countries (mainly from the US) are high, as reflected in the following graph:**



Source: CMIE Industry outlook

- Indian manufacturers are losing out to the Chinese as they offer cheaper prices. Additionally, Indian companies are not able to bid for Chinese tenders as China has a clear policy for supporting its domestic devices.

- The inverted duty structure is a big blow for muted growth in the Indian medical devices industry as the finished goods are cheaper to import rather than raw materials/components used for manufacturing. Moreover, as there is a lower import duty on second-hand imports, India sees considerable second-hand imports from China and elsewhere in the world, of older devices, which are dumped into our hospitals. In a few years, they expire, and it is tough to find spare parts to repair older devices.

- Although the pandemic has taught required lessons, government intervention is required to reduce import dependence in this industry.

Lessons from COVID-19

There is a saying, that a crisis unfolds the truth and brings in dark reality, but it also provides opportunities for the way forward.

- The year 2020 has been by Coronavirus, and this crisis has made every country realise where it stands on the healthcare and medicines front. The sector that underwent a deeper crisis is the medical devices industry.

- One of the key reasons the medical supply chain is largely affected by COVID-19 is that it is built on a Just-In-Time (JIT) philosophy.

- Supply chains based on reliable and timely deliveries are susceptible to unforeseen disruptions on a wide scale. As the outbreak turned into a pandemic, demand for medical equipment far outweighed supplies due to the speed of infection spread.

- There were suggestions on making the medical supply chain more flexible by holding more inventory in the event of such outbreaks. However, it will be difficult for hospitals to stay away from hoarding as the advantages from JIT operations are too substantial to be overlooked.

- Secondly, medical devices and supplies are also increasingly reliant on China's ecosystem. During the COVID-19 outbreak, with supply disruptions from China, the risk of medical shortage problems became more prominent. Chinese medical products are difficult to be replaced as they are cheap and of good quality. In particular, dependence on China for certain product categories and reasons for the same are highlighted above.

- Medical devices being a critical healthcare need, India needs to develop its own medical device sector and reduce its dependence on imports, and for this purpose, come out with a medium- to long-term strategy.

Current Regulatory Framework for Indian Medical Device Industry

- The Central Drugs Standard Control Organisation (CDSCO) published the Medical Devices Rules, 2017, which came into force on 1 January 2018.
- These rules were deemed to simplify the regulatory structure to obtain registration and licenses by importers and manufacturers of 'medical devices', which were distinguished for the first time since the Drugs and Cosmetics Act,1940, was enacted.
- It introduced a risk-based classification system and product standards for medical devices, single window clearance, and certain and rationalised timelines for obtaining registration and licenses.
- It also consolidated the requirement of obtaining registration certificate and import license into a single license for foreign manufacturers.
- On 11 February 2020, the Ministry of Health and Family Welfare (MoH&FW) issued two notifications in the Indian Gazette – a new definition of medical devices and The Medical Devices (Amendment) Rules, 2020; the latter amends the Medical Devices Rules, 2017, and has been effective from 1 April 2020.
- The Ministry after consultation with the Drugs Technical Advisory Board (DTAB) has intended for a cumulative effect of both these notifications to ensure that all medical devices meet certain standards of quality and efficacy, and for the mandatory registration of all medical devices.
- The notification calls for registration within a period of 18 months from April 2020 and obtaining manufacturing/import licence under the Medical Device Rules within 36 months for some devices and 42 months for others.
- This would mean that every medical device, either manufactured in India or imported, will have to have quality assurance before it can be sold anywhere in the country.
- These rules adhere to the Global Harmonisation on Task Force (GHTF) and are in line with global standards.
- These rules are expected to improve the perception of medical devices manufactured in India and help in quality improvement.

In-house R&D and Skill Development Opportunities

- Innovation is an important factor to lead the medical devices industry on a consistent growth track, and India, which has a large young talent pool of engineers, can take the lead in related research and development.

- However, in terms of the global footprint of R&D in the medical device sector, India contributes only 6%, and North America and Europe boast of the largest contribution standing, at a staggering ~90%. Going a step further, it is clear that medical devices R&D is consolidated in the US and is not very globalised.

- However, the shift is slowly visible, with OEMs starting to expand R&D globally by setting-up centres across geographies. In India, Bangalore and NCR have emerged as the two major hotspots for medical device investments.

- In India, GE Health Care, Philips and Boston Scientific Health Care have established their global in-house centres and are combining innovation and scale to support product development for both global and emerging markets. This means R&D efforts are catered to meet three key endpoints: India for global, India for the region and India for local. This can help ensure scalability of products and encourage better investment in R&D in the years to come.

- Although a strong talent base exists in software and engineering, there is a clear innovation gap, and universities/academics are to develop suitable syllabus to enhance skill development in this area.

- Under the Indian Ministry of Skill development and Entrepreneurship (MSDE), the Healthcare Skill Sector Council caters to the requirements of health and medical device subsectors. The council has a mandate to create occupational skill standards and works along with industry partners. They create qualification packs, which set validated standards for each skill and criterion. These then enter the National Qualification Register. Exams are conducted by the Skill Council, and certificates are issued to students for placement.

- Many skill development programmes are being conducted by the government and private sector to enhance the quality of skilled personnel in the medical device sector. For example, NIPER Ahmedabad has a National Centre for Medical Devices (NCMD) for the development of skilled manpower in the manufacture of medical devices.

Need for Atmanirbar

- There is an immediate need to minimise import and attain self-reliance in domestic manufacturing so as to ensure uninterrupted availability of healthcare.

- India is still an untapped market, and healthcare is at the nascent stage. There is significant scope for deeper penetration and to tap the unmet domestic demand.

- Opportunities are emerging in exports as India continues to be a low-cost manufacturing hub.

- With significant skilled manpower in place, good opportunities exist to realise potential and enable higher skill development.

- Better forex and competitiveness could be gained if self-sufficiency in domestic production is achieved.

Atmanirbar on Medical Devices Industry

The Government of India, (Department of Pharmaceuticals under Ministry of Chemicals) recognises that the medical device sector in India suffers from a considerable cost of manufacturing disability, vis-a-vis competing economies, inter alia, on account of the lack of adequate infrastructure, domestic supply chain and logistics, high cost of finance, inadequate availability of power, limited design capabilities and low focus on Research and Development (R&D), among others. Thus, a need was felt for a mechanism to compensate for this manufacturing disability to ensure a level playing field for the domestic manufacturers of medical devices. To compensate for the manufacturing disability in the selected segments of medical devices, GOI has come out with the PLI Scheme for promoting the domestic manufacture of medical devices.

The detailed guidelines under this scheme are as follows:

<table>
<tr><th>Particulars</th><th>Details</th></tr>
<tr><td>Tenure</td><td>2020-21 to 2027-2028</td></tr>
<tr><td>Total outlay</td><td>Rs.3,420 crore</td></tr>
<tr><td>Quantum of incentives</td><td>

5% on incremental sales for manufactured goods from FY 2022-2023. Incremental sales are the sales of manufactured goods over a given period minus the sales of the manufactured goods in the base year over the corresponding period.
Financial year 2019-2020 shall be treated as the base year for manufactured goods.
Minimum incremental sales and maximum incentives year-wise are as follows:

<table>
<tr><th>Year</th><th>Incremental sales (Rs. Crore)</th><th>Maximum Incentives</th></tr>
<tr><td>2022-23</td><td>60</td><td>8</td></tr>
<tr><td>2023-24</td><td>120</td><td>17</td></tr>
<tr><td>2024-25</td><td>180</td><td>27</td></tr>
<tr><td>2025-26</td><td>230</td><td>32</td></tr>
<tr><td>2026-27</td><td>280</td><td>37</td></tr>
</table>
Total maximum incentive is Rs.121 crore
</td></tr>
<tr><td>Eligible product segments</td><td>
<table>
<tr><th>Target Segment</th><th>Description of Medical Devices</th></tr>
<tr><td>Segment 1</td><td>Cancer care/radiotherapy medical devices</td></tr>
<tr><td>Segment 2</td><td>Radiology and imaging medical devices (both</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td></td><td>ionizing and non-ionizing radiation products) and nuclear imaging devices</td></tr>
<tr><td>Segment 3</td><td>Anaesthetics and cardio-respiratory medical devices including catheters of cardio respiratory category and renal care medical devices</td></tr>
<tr><td>Segment 4</td><td>All implants including implantable electronic devices such as cochlear implants and pacemakers</td></tr>
</table>

A key component that constitutes the major part of a finished medical device (such as rotating anode tube, stationary anode tube, mri magnet, flat panel detector and similar components) and has a distinct HS code for itself will be considered as included in the corresponding target segment.</td></tr>
<tr><td>Minimum committed investment</td><td>For claiming incentives, the selected entity has to commit a minimum threshold investment of Rs. 180 crore over a period of three years. (First year- Rs.60 crore, Second year- Rs.120 crore and Third year- Rs.180 crore)</td></tr>
<tr><td>Applicant's eligibility</td><td>● A maximum of 28 applicants shall be selected under this scheme.
● A minimum of 3 and maximum of 10 applicants shall be selected under each target segment.
● Should not have been declared bankrupt/wilful defaulter/defaulter/fraud by any bank/FI/NBFC
● The Net-worth of the applicant should not be less than 30% of the proposed investment.</td></tr>
<tr><td>Evaluation criteria</td><td>● Evaluation criteria are determined on the following four parameters:
A. Manufacturing turnover of the applicant /group company for the base year FY 2019-2020
B. Existing patent/technology transfer
C. Existing 13845/product approval in CDSCO/AERB approved/regulatory product approval in the US, the UK, Australia, Japan, Canada, the European Union
D. Average R&D expenses for the period 2017-18 and 2018-19 as a percentage of sales revenue
● All eligible applicants shall be ranked on the basis of marks obtained in the evaluation criteria.
● In case the applicants share the same score, selection shall be made on the global manufacturing turnover for FY 2019-20.
● The number of selected applicants shall be limited by the maximum incentive available for each eligible product.</td></tr>
</table>

Computation of incentive	• **Incentive shall be calculated as follows: Net sales of eligible product * Rate of incentive** • **Eligible products are products as stated in the approval letter.** • **The Net sales of eligible products mean the sale of eligible products manufactured by the applicant in the Green field project approved and set-up under these guidelines.** • **Incremental sales mean the sales of the eligible product for that particular year to which the claim for disbursement pertains minus the net sale of the eligible products for the base year.**
Other details	• **IFCI Ltd has been appointed as the** • **Applications are scrutinised by the PMA and selected by the empowered committee.** • **The selected applicant has to furnish a bank guarantee to the tune of 1% on the committed investment.** • **The disbursement of incentives is done half yearly/annually.**

Government Notification: The government vide its notification dated 11 February 2021 has approved nine applications under four target segments, which are as follows:

Sl.No	Name of the approved Applicant	Name of Eligible product	Committed Investment (Rs.crs)
1	M/s Siemens Healthcare Private Limited	CT Scan and MRI	91.91
2	M/s Allengers Medical	CT Scan, MRI,	50

	Systems Limited (AMSL)	Ultrasonography, X-Ray, Cath Lab, Positron Emission Tomography (PET) Systems, Single Photon Emission, Mammography and C arm	
3	M/s Allengers OEM Private Limited (AOPL)	X Ray Tubes, Collimators, Flat Panel Detector and Monitors	40
4	M/s Wipro GE Healthcare Private Limited (WGHPL)	CT Scan, Cath Lab and Ultrasonography	50.22
5	M/s Nipro India Corporation Private Ltd (NICPL)	Dialyzer	180
6	M/s Wipro GE Healthcare Private Limited (WGHPL)	Anesthesia Unit Ventilator and Patient Monitor	53.86
7	M/s Sahajanand Medical Technologies Private Limited (SMTPL)	'Heart Valves', 'Stents', 'PTCA Balloon Dilatation Catheter' and 'Heart Occluders'	166.89
8	M/s Innvolution Healthcare Private Ltd (IHPL)	'Stents' and 'PTCA Balloon Dilation Catheter'	21.75
9	M/s Integris Health Private Limited (IHPL) for Eligible Products	Transcatheter Aortic Heart Valve	75

Notification 2: The government vide notification dated 03 March 2021, has approved five other applications cumulating to a committed investment of Rs. 873.93 cr., which will lead to the utilisation of the maximum incentive of about Rs1,694 cr., against the total budget outlay of Rs. 3,420 cr. The government has decided to re-invite applications for the uncovered/ under-covered products in the PLI Schemes for bulk drugs and medical devices for utilising the approved outlay.

Medical Devices Park

Medical Devices Park is a designated contiguous area of land with common infrastructure facilities for the exclusive manufacture of medical devices.

The common facilities are with capacity commensurate with the expected number and type of medical device manufacturing units in the park. Some of the indicative activities under the common facilities/centres are as follows:

a) Component testing centre/ESDM/PCB/sensors facility

b) Electro-magnetic interference and electro-magnetic compatibility centre

c) Biomaterial/biocompatibility/accelerated aging testing centre

d) Medical grade moulding/milling/injection moulding/machining/tooling centre

e) 3D designing and printing for medical grade products.

These parks are intended to be created with the following objectives:

A. The creation of world-class infrastructure facilities to make the Indian medical device industry a global leader

B. Easy access to standard testing and infrastructure facilities through the creation of world class common infrastructure facilities for increased competitiveness will result in a significant reduction in the cost of production of medical devices, leading to the better availability and affordability of medical devices in the domestic market.

C. The utilisation of the benefits arising from the optimisation of resources and economies of scale

The details of the Atmanirbar scheme in the medical parks category are as follows:

Particulars	Details
Duration of the scheme	FY 2020-21 to FY 2024-25
Number of Parks	Maximum of four parks are supported under this scheme
Total financial outlay	Rs. 400 crores.; Maximum Rs.100 crore per park
Grant in Aid	The grant-in-aid will be 70% of the project cost of the common infrastructure facilities (CIF). In case of North Eastern and hilly states (i.e., Himachal Pradesh, Uttarakhand, the UT of Jammu & Kashmir and the UT of Ladakh), the grant-in-aid will be 90% of the common infrastructure facilities.
Project cost	Cost of setting-up common infrastructure facilities in the park
Basis of Eligibility	States to be ranked based on 11 factors, including utility charges, state policy infrastructure, connectivity, lease rate, area of the proposed park, power and water availability, stamp duty and registration charges, ease of doing business ranking and availability of technical manpower, among others
Implementing Agency	The SIA shall be a legal entity set-up by the state government for the purpose of implementing the Bulk Drug Park Project.

***** States that have applied for include Tamil Nadu, Andhra Pradesh, Himachal Pradesh, Gujarat, Telengana and Rajasthan. The Department of Pharmaceuticals is yet to come up with the shortlisted applicants under the Medical Device Park.

BWR Standpoint

- **Atmanirbharta (self-reliance) in medical devices is critical for the healthcare industry of a large country such as India; unfortunately, the importance of this sector has not been acknowledged for a long time now.**

- **The Atmanirbar package announced by the Government of India is providing both financial and infrastructure incentives to eligible companies to reduce the major bottlenecks and ensure the smooth flow of domestic production in critical device manufacturing.**

- **The Atmanirbar package is just the first step to address the starved sector, and many more government interventions are required in areas such as the protection of intellectual property rights, product liability, steps to enhance frugal innovation, favourable customs tariff for raw materials, higher import duty for equipment, price cap on medical devices, and so on, which shall incentivise domestic producers to ramp up their production.**

- **India's healthcare industry is growing at a faster pace with increasing coverage and service, and higher expenditure incurred both by public and private players. While the demand side is buoyant, the same needs to be contributed by an uninterrupted supply side, which has to be ramped up effectively through domestic production to minimise disruptions and ensure continuity.**

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