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**Newsflash : Schemes for Development of  
Pharmaceuticals Industry**

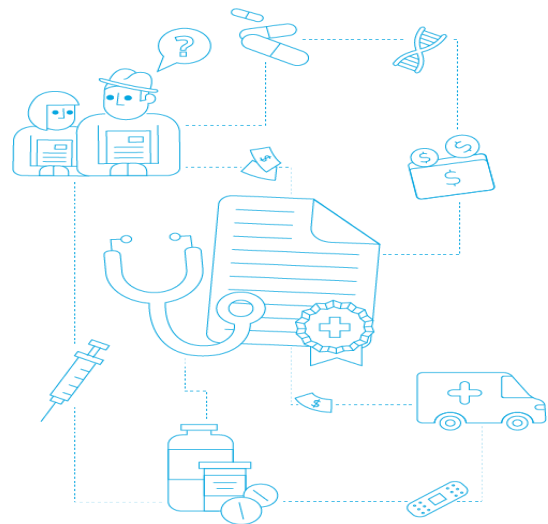
## Newsflash

### Schemes for Development of Pharmaceuticals Industry

For Client Circulation  
25 August 2020

#### 1.0 Background

The Department of Pharmaceuticals released four schemes in relation to development of bulk drugs and medical device parks to promote domestic manufacturing in pharmaceutical industry. The objective is to make India self-reliant in the production of Active Pharmaceutical Ingredients (APIs) or Key Starting Materials (KSMs) or Drug Intermediates (DIs) and in production of medical devices. The objective is in line with the “Atmanirbhar Bharat” vision of Prime Minister Narendra Modi.

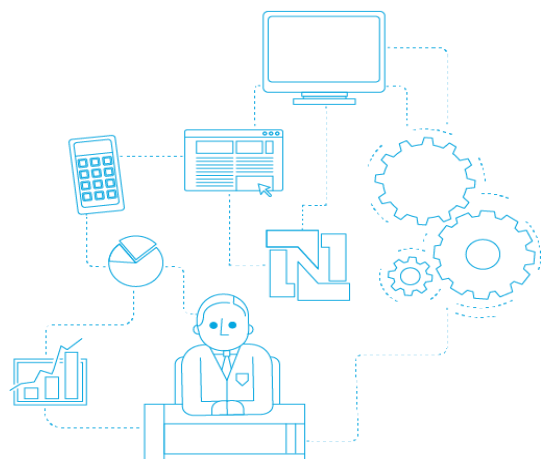


The medical device industry is highly capital intensive with a long gestation period and requires development and induction of new technologies. Further, domestic medical device market in India is heavily dependent on imports which contribute to more than 85% of the market. Similarly, India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during FY 2018-19. With a view to attain self-reliance and reduce import dependence for medical device industry and pharmaceutical industry, these schemes have been introduced.

#### 2.0 Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs or DIs or APIs.<sup>1</sup>

##### 2.1 Objective

The scheme intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reducing India’s import dependence in critical APIs. Total financial outlay of the scheme is INR 6,940 crores.



<sup>1</sup> <https://pharmaceuticals.gov.in/schemes>

## 2.2 Quantum of Incentive

Financial incentive under the scheme shall be provided towards sales of 41 identified products for 6 years at the rates given below:

Type	Year	Incentive
Fermentation based products	FY-2023-24 to FY-2026-27	20%
	FY-2027-28	15%
	FY-2028-29	5%
Chemical Synthesis Based products	FY-2022-23 to FY-2027-28	10%

## 2.3 Tenure of the Scheme

The tenure of the scheme is from FY 2020-21 to FY 2029-30 and base year would be 2019-20.

## 2.4 Target Segments

Financial incentives shall be given based on sales made by selected manufacturers for 41 products. Four Target Segments mentioned covering 41 products are explained in **para 2.5 – eligibility of incentive.**

1. Fermentation based KSMs/DIs
2. Fermentation based niche KSMs or DIs or APIs
3. Key Chemical Synthesis based KSMs or DIs
4. Other Chemical Synthesis based KSMs or DIs or APIs

## 2.5 Eligibility for incentive

A selected applicant must meet both the eligibility criteria of threshold investment and minimum annual production capacity as follows:

The following <b>Fermentation based 04 KSMs /DIs</b> will be required to meet INR 400 Crores investment criteria <b>(with maximum 2 applicant to be selected for each drug)</b>					
S. No.	Name of KSM/DI/API	Minimum annual Production Capacity (Metric Tonnes)	S. No.	Name of KSM/DI/API	Minimum annual Production Capacity (Metric Tonnes)
1	Penicillin G	5000	3	Erythromycin Thiocynate (TIOC)	800
2	7-ACA	1000	4	Clavulanic Acid	1.5 lakh Kg

The following **Fermentation based niche KSMs or DIs or APIs** will be required to meet INR 50 Crores investment criteria **(with maximum 2 applicant to be selected for each drug)**

S. No.	Name of KSM/DI/API	Minimum annual Production Capacity (Metric Tonnes)	S. No.	Name of KSM/DI/API	Minimum annual Production Capacity (Metric Tonnes)
5	Neomycin	175	10	Rifampicin	100
6	Gentamycin	40	11	Vitamin B1	200
7	Betamethasone	2	12	Clindamycin Base	60
8	Dexamethasone	2	13	Streptomycin	50
9	Prednisolone	15	14	Tetracycline	450

The following **Key Chemical Synthesis based KSMs or DIs** will required to meet INR 50 Crores investment criteria **( with maximum 4 applicant to be selected for each drug)**

S. No.	Name of KSM/DI/API	Minimum annual Production Capacity (Metric Tonnes)	S. No.	Name of KSM/DI/API	Minimum annual Production Capacity (Metric Tonnes)
15	1,1 Cyclohexane Diacetic Acid (CDA)	1500	17	Dicyandiamide (DCDA)	8000
16	2-Methyl-5Nitro-Imidazole (2-MNI)	800	18	Para amino phenol	8000

The following **Other Chemical Synthesis based KSMs or DIs or APIs** will required to meet INR 20 Crores investment criteria **(with maximum 4 applicant to be selected for each drug)**

S. No.	Name of KSM/DI/API	Minimum annual Production Capacity (Metric Tonnes)	S. No.	Name of KSM/DI/API	Minimum annual Production Capacity (Metric Tonnes)
19	Meropenem	10	31	Aspirin	2800
20	Atorvastatin	30	32	Diclofenac Sodium	175
21	Olmesartan	25	33	Levetiracetam	140
22	Valsartan	25	34	Carbidopa	2

23	Losartan	80	35	Ritonavir	5
24	Levofloxacin	115	36	Lopinavir	7
25	Sulfadiazine	20	37	Acyclovir	175
26	Ciprofloxacin	300	38	Carbamazepine	65
27	Ofloxacin	100	39	Oxcarbazepine	65
28	Norfloxacin	15	40	Vitamin B6	35
29	Artesunate	35	41	Levodopa	10
30	Telmisartan	80			

**Note:** The Net Worth of the Applicant (including that of Group Companies), as on the date of application, shall not be less than 30% of the total proposed investment.

- The proposed Domestic Value Addition (DVA) by the applicant shall be at least 90% in case of fermentation based product and at least 70% in case of chemical synthesis based product

## 2.6 Applicability

The scheme is applicable only for greenfield projects. A greenfield project means project(s) wherein investment equal to or more than threshold investment is proposed to be made by the applicant under this Scheme in a new production facility or in a new plant in the premises of an existing production facility.

## 2.7 Application window

The application window shall be open for 120 days from the date of issuance of guidelines i.e. from 27 July 2020.

## 2.8 Application Fee

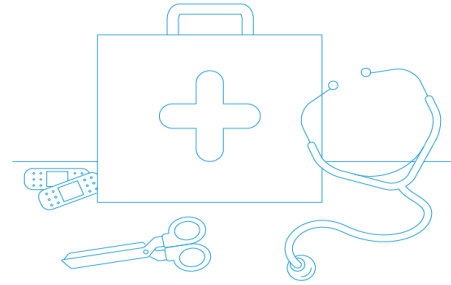
Application Fee under the Scheme shall be as under:

Sr. No	Name of the eligible Product	Application Fee
1	Penicillin G, 7-ACA, Erythromycin Thiocynate (TIOC), Clavulanic Acid	INR 1,00,000
2	All other eligible products	INR 50,000

### 3.0 **PLI Scheme for Medical Devices<sup>2</sup>**

#### 3.1 **Objective**

The Scheme intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. Total financial outlay of the Scheme is INR 3,420 crores.



#### 3.2 **Quantum of Incentive**

Under the Scheme, financial incentive shall be given to selected companies at the rate of 5% of incremental sales over Base Year of goods manufactured in India and covered under Target segments, for a period of 5 years i.e. from FY 2021-22 to FY 2025-26.

#### 3.3 **Target Segments**

The Scheme is applicable only for target segments of medical devices as detailed below:

Name of the Segment	Indicative Eligible Products
Cancer care/Radiotherapy medical devices	Brachytherapy Systems, Rotational Cobalt Machine, Radiotherapy Simulation Systems, Linear Accelerator (LINAC), Workstations- Radiotherapy Planning, Proton therapy system and other products* in this target segment
Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	CT Scan, MRI, Ultrasonography, X-ray equipment, mammography, C-arm, Cath-Lab, Positron Emission Tomography (PET) Systems, Single photon emission tomography (SPECT), Cyclotrons and other products* in this target segment.
Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices	Needles-Anesthesia, Syringes-Anesthesia, Anesthesia workstation, Anesthesia Unit Gas Scavengers, Anesthesia Kits, Masks —Anesthesia, Anesthesia Unit Vaporizers, Anesthesia Unit Ventilators, Automated external defibrillators (AEDs), Dialyzer, Dialysis Machine, Peritoneal dialysis kits, Biopsy Kits-Renal, Dialyser reprocessing I Lithotripters-Extracorporeal — Renal and other products* in this target segment.
All Implants including implantable electronic devices like Cochlear	Cochlear Implants, Hip Implants, Knee implants, Spinal and neuro-surgical implants, Urogynecologic Surgical Mesh Implants, Hernia Surgical Mesh Implants, Cerebral Spinal Fluid

<sup>2</sup> <https://pharmaceuticals.gov.in/schemes>

Implants and Pacemakers	(CSF) Shunt Systems, Implanted Pacemakers, insulin pump, implanted neuro-stimulated device like Deep Brain Stimulator, Intraocular lenses, heart valves, stents and other products* in this target segment.
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*\*Other products — For products not specifically mentioned in the table above the Technical Committee shall decide whether such products shall be considered eligible under the Target Segment.*

**Note:** A key component which constitutes 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

### 3.4 Applicability

The Scheme is applicable only for greenfield projects. A greenfield project means a project wherein minimum threshold investment is proposed to be made by the applicant under this Scheme in a new production facility or in a new plant in the premises of an existing production facility.

### 3.5 Eligibility for scheme

Financial incentive under the scheme shall be provided only to companies engaged in manufacturing of goods covered under target segments in India

### 3.6 Eligibility for incentive

Eligibility shall be subject to thresholds of investment and incremental sales of manufactured goods (covered under Target Segments) over Base Year. The Eligibility Threshold Criteria is given below :

Segment	Incentive Rate (on Incremental Sales of Manufactured Goods)	Threshold Minimum Investment	Threshold Minimum Incremental Sales of Manufactured Goods
All four segments of medical devices explained in para 3.3	Year 1: 5% Year 2: 5% Year 3: 5% Year 4: 5% Year 5: 5%	INR 180 Crores over 3 Years Cumulative Minimum (Crores): Year 1: 60 Year 2: 120 Year 3: 180	Year 1: INR 120 Crores Year 2: INR 240 Crores Year 3: INR 360 Crores Year 4: INR 460 Crores Year 5: INR 560 Crores

**Note1:** Year 1 means Financial Year 2021-22

**Note2:** Financial Year 2019-20 shall be treated as the base year

**Note3:** Only companies registered in India and having Net Worth (of applicant company including that of Group Companies) not less than Rs.18 crores (i.e. 30% of the threshold investment for the first year) as on the date of application are qualified to apply under the Scheme.

### 3.7 Tenure of the Scheme

The tenure of the scheme is from FY 2020-21 to FY 2026-27.

### 3.8 Application Window

The application window for receiving the applications shall be 120 days

### 3.9 Application fee

An application fee of INR 1,00,000 under this scheme.

## 4.0 Scheme for Promotion of Medical Device Parks<sup>3</sup>

### 4.1 Objective

World class common infrastructure facilities will provide easy access to standard testing and infrastructure facilities which will result into to better availability and affordability of medical devices in the domestic market at competitive prices. The total financial outlay of the scheme is INR 400 crores.



### 4.2 Scope

Financial assistance under the Scheme will be provided for creation of common infrastructure facilities in four Medical Device Parks proposed by State Governments and selected under the scheme.

### 4.3 Financial Assistance

Financial assistance to a selected Medical Device Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Medical Device Park would be limited to INR 100 crores.

### 4.4 Common Infrastructure Facilities

The common facilities provided to individual medical device units in the Medical Device Park such as component testing center/ESDM/PCB/sensors facility, electro-magnetic interference & electromagnetic compatibility center, biomaterial/biocompatibility /accelerated aging testing

<sup>3</sup> <https://pharmaceuticals.gov.in/schemes>



center, medical grade moulding/milling/injection moulding/machining/tooling center, 3D designing and printing for medical grade products, sterilization/ETO/gamma center, animal lab and toxicity testing center, radiation testing center etc.

#### **4.5 Tenure of the Scheme**

The tenure of the scheme is from FY 2020-2021 to FY 2024-2025.

### **5.0 Scheme for Promotion of Bulk Drug Parks<sup>4</sup>**

#### **5.1 Objective**

Easy access to world class common infrastructure facilities to bulk drug units located in the parks will significantly bring down the manufacturing cost of bulk drugs. Consequently, increase the competitiveness of the domestic bulk drug industry. The total financial outlay of the Scheme is INR 3,000 crores.

#### **5.2 Scope**

Financial assistance under the Scheme will be provided for creation of common infrastructure facilities in three Bulk Drug Parks proposed by State Governments and selected under the scheme.

#### **5.3 Financial Assistance**

Financial assistance to a selected Bulk Drug Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Bulk Drug Park would be limited to INR 1000 crores.

#### **5.4 Common Infrastructure Facilities**

The common facilities provided to individual bulk drug units in the Bulk Drug Park such as central effluent treatment plant, solvent recovery and distillation plant, steam generation and distribution system, common cooling system and distribution network, common logistics facilities, advance laboratory testing centre, emergency response centre, centre of excellence etc.

#### **5.5 Tenure of the Scheme**

The tenure of the Scheme is from FY 2020-2021 to FY 2024-2025.

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<sup>4</sup> <https://pharmaceuticals.gov.in/schemes>

## 6.0 Our Comments

Indian pharmaceutical industry is the 3rd largest in the world by volume and 14th largest in terms of value. India contributes 3.5% of total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations.

Drugs play a vital role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supply of drugs can have significant adverse impact on drug security of the country. Therefore, schemes introduced for the bulk drug manufacturing for the 53 Critical APIs and the development of bulk drug parks in India will make India self-reliant in Pharma Sector instead of depending upon the imports of various drugs.

The Medical Device industry is highly capital intensive with a long gestation period and requires development and induction of new technologies. Most of the hi-tech innovative products originate from a 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%. PLI Scheme for promoting domestic manufacturing of Medical Devices will compensate for the manufacturing disability in selected segments of medical devices. Further, medical device parks will provide common testing and laboratory facilities centre at one place to reduce the manufacturing cost significantly and create a robust ecosystem for medical device manufacturing in India.

All the four schemes are a great initiative by Government of India to boost the Pharma and Healthcare sector in India. These schemes will also help in generation of employment opportunities in India and becoming self-reliant India in Pharma and Healthcare sector.

Further, with effect from FY 2019-20, any new domestic companies incorporated on or after 1 October 2019 making fresh investment in manufacturing have an option to pay income-tax at the rate of 15% with an effective tax rate of 17.01% (inclusive of surcharge & cess). Also, such companies shall not be required to pay Minimum Alternate Tax. This benefit is available to companies which do not avail any exemption/incentive under the Income-tax Act, 1961 and commence their production on or before 31 March 2023. Such reduction in tax rate coupled will create an opportunity for new manufacturing players and provide a level playing field with global giants existing in the world ecosystem.

As the schemes are open for a limited time period, companies willing to apply for the scheme should analyze the cost-benefits at the earliest in order to avail the incentives as laid down under all the four schemes.

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This newsflash has summarized on the schemes for Medical devices and bulk drug manufacturing and development of parks. It may be noted that nothing contained in this newsflash should be regarded as our opinion and facts of each case will need to be analyzed to ascertain applicability or otherwise of the said notification and appropriate professional advice should be sought for applicability of legal provisions based on specific facts. We are not responsible for any liability arising from any statements or errors contained in this newsflash.

25 August 2020