

Approvals accorded under Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country

Press Information Bureau: April 15, 2021

Approvals have been accorded to 16 applicants under Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country. The setting up of these 16 plants will lead to total committed investment of Rs. 348.70 crore (US\$ 46.39 million) and employment generation of about 3,042 by the companies. The commercial production of these plants is projected to commence from 1st April 2023 onward.

The applications of following companies, which have committed minimum/more than the minimum proposed annual production capacities and fulfil the prescribed criteria, have been approved, as under (under Target Segment IV):

S.No.	Name of Eligible Product	Name of the Applicants	Committed production capacity (in MT)	Committed Investment (Rs. in crore)
1	Valsartan	Honour Lab Limited	300	26.88
2	Losartan	Anasia Lab Private Limited	400	29.12
3	Levofloxacin	Hetero Drugs Limited	230	9.00
4		Chemex Global	115	20.00
5		Surya Life Sciences Limited	230	20.00
6	Sulfadiazine	Andhra Organics Limited	360	38.70
7	Ciprofloxacin	Sreepathi Pharmaceuticals Limited	900	16.05
8	Ofloxacin	Sreepathi Pharmaceuticals Limited	300	16.05
9		Global Pharma Healthcare Private Limited	200	16.49
10	Telmisartan	Andhra Organics Limited	360	40.00

11	Diclofenac Sodium	Kreative Actives Private Limited	350	20.74
12		Amoli Organics Private Limited	175	6.56
13		Vapi Care Pharma Private Limited	525	21.00
14	Levetiracetam	Honour Lab Limited	840	31.36
15	Carbidopa	Hetero Drugs Limited	16	18.00
16	Levodopa	Hetero Drugs Limited	40	18.75

With an objective to attain self-reliance and reduce import dependence in these critical Bulk Drugs - Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country, the Department of Pharmaceuticals had launched a Production Linked Incentive (PLI) Scheme for promotion of their domestic manufacturing by setting up greenfield plants with minimum domestic value addition in four different Target Segments (In Two Fermentation based - at least 90% and in the Two Chemical Synthesis based - at least 70%) for 41 products with a total outlay of Rs. 6,940 crore for the period 2020-21 to 2029-30.

In total, 215 applications were received for the 36 products spread across the 4 Target Segments. The applications under the target Segments I, II and III were considered and eligible applications approved in earlier meetings of the Empowered Committee. Out of total 174 applications received for 23 Eligible Products under Target Segment IV - Other Chemical Synthesis Based KSMs/ Drug Intermediates/APIs, 79 applications received for 11 eligible products were considered earlier and 14 applications approved in the sixth meeting of the Empowered Committee. In the 7th Meeting of the Empowered Committee held on 19.03.2021 the remaining 95 applications under the Target Segment IV were considered.

With this, all the 215 applications received have been considered and a total of 47 applications (excluding 2 successful applications withdrawn subsequently) with committed investment of Rs. 5366.35 crore (US\$ 713.95 million) have been approved by the Government under the PLI Scheme for Active Pharmaceutical Ingredients (APIs). Setting of these plants will make the country self-reliant to a large extent in respect of these Bulk drugs. The disbursement of production linked incentive by the Government over the six years period would be up to a maximum of about Rs. 6,000 crore against the budgetary outlay of Rs. 6940 crore (US\$ 923.31 million).

Under the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, after considering all 28 applications, 14 applications have been approved by the Government with a committed investment of Rs. 873.93 crore which will lead to utilization of maximum incentive of about Rs. 1,694 crore against total budget outlay of Rs. 3,420 crore. 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 utilizing the approved outlay.

The Indian pharmaceutical industry is the 3rd largest in the world by volume. It has high market presence in several advanced economies such as the US and EU. The industry is well known for its production of affordable medicines, particularly in the generics space. However, the country is significantly dependent on the import of basic raw materials, viz., Bulk Drugs that are used to produce medicines. In some specific bulk drugs, the import dependence is 80 to 100%.