

No. 31026/16/2020-Policy
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
NOTIFICATION

New Delhi, the 2nd June, 2020

Subject:- Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) In India.

1. Background

1.1. The mandate of the Department is to promote pharmaceutical industry and to ensure availability of drugs at affordable prices.

1.2. Medicines play a major 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 supplies can have significant adverse impact on Drug Security, which is also linked to the overall economy of the country. Self-sufficiency in manufacturing of bulk drugs is highly required.


1.3. Future growth of pharma sector is contingent upon our ability to ensure uninterrupted supplies of quality of Active Pharmaceutical Ingredients and also our ability to upscale the manufacturing to meet emergency situations. India could only become the true pharmacy of the world by ensuring this.

1.4. The Indian pharmaceutical industry is the 3rd largest in the world by volume. India contributes 3.5% of total drugs and medicines exported globally with a ranking of 14 in terms of value. However, despite these achievements, India is significantly dependent on import of basic raw materials, viz., Active Pharmaceutical Ingredients (API) that are used to produce the Finished Dosage Formulations. APIs accounted for 63% of the total pharmaceutical imports in the country during 2018-19. India imports APIs largely for economic considerations.

1.5. In order to ensure drug security in the country, a Drug Security Committee constituted by the Department of Pharmaceuticals collated the details of KSMs/APIs imported in the country and identified 58 KSMs/APIs for which the country is heavily dependent on imports.

1.6. Department of Pharmaceuticals further constituted a Technical Committee to recommend government support in terms of incentives required to be provided to indigenous pharmaceutical industry to ensure drug security in the country. Committee made various recommendations and also identified 53 KSMs/APIs based on the therapeutic criticality, essentiality, technology involved and feasibility to manufacture indigenously. A list of 53 identified KSMs/APIs is attached as **Annexure A**.

1.7. Government, with its aim to attain self-reliance and Drug Security, has agreed to provide incentives to boost manufacture of KSMs/DIs/APIs in the country.

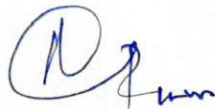


2. **Objective:** The scheme intends to boost domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs.
3. **Quantum of Incentive:** Support under the scheme shall be provided for six years in case of fermentation based products and five years of chemically synthesized products.

For fermentation based eligible products, incentive for first four years (2022-2023 to 2025-2026) would be 20%, for fifth year (2026-27) incentive would be 15% and the sixth year (2027-2028) incentive would be 5%; on incremental sale of KSMs/Drug Intermediates/APIs.

For chemically synthesis eligible products, incentive for five years (2021-2022 to 2025-2026) would be 10% on incremental sales of KSMs/Drug Intermediates/APIs.

4. **Target Segments:** The Scheme shall only be applicable for target segments of critical KSMs/Drug Intermediates and APIs as detailed in **Annexure B**.
5. **Eligibility:** Support under the scheme shall be provided only to manufacturers of critical KSMs/Drug Intermediates and APIs in India.
 - 5.1 Eligibility shall be subject to threshold of incremental investment for manufacturing critical KSMs/Drug Intermediates and APIs (as distinct from traded critical KSMs/Drug Intermediates and API).
 - 5.2. Eligibility under the scheme shall not affect eligibility under any other scheme and vice-versa.
 - 5.3. The scheme is applicable only for greenfield projects.
6. **Tenure of the Scheme:** The tenure of the scheme will be for a period of eight years from 2020-21 to 2027-28 subsequent to the base year.
 - 6.1. The Scheme shall be open for applications for a period of 4 months.
 - 6.2. The application window may be reopened if the initial round does not have enough applications.
7. **Base Year:** Financial Year 2019-20 shall be treated as the base year for computation of incremental sales of identified critical KSMs/Drug Intermediates and APIs.
8. **Incentive Outlay:** Total outlay of Rs. 6940 Crore will be provided as incentive during the tenure of the scheme.



9. Basis of Computation:

9.1. Assessment of incremental investment and sales of manufactured KSMs/Drug intermediates and APIs shall be based on details furnished to the Departments / Ministries / Agencies and Statutory Auditor certificates.

9.2. Functional Guidelines will be issued by Department of Pharmaceuticals (DoP) in consultation with concerned Departments / Ministries.

10. Approval and Disbursement Process:

10.1. Application under the Scheme can be made by any company registered in India.

10.2. An initial application, complete in all aspects, will have to be submitted before the due date. Acknowledgement will be issued after initial scrutiny of the application. The acknowledgement shall not be construed as approval under PLI Scheme.

10.3. Eligible applications will be appraised on an ongoing basis and considered for approval.

10.4. Incentive shall be released to eligible applicants, meeting the required thresholds and whose disbursement claims are found to be in order.

11. Nodal Agency:

11.1. The Scheme shall be implemented through a Nodal Agency.

11.2. Such Nodal Agency shall act as a Project Management Agency (PMA) and be responsible for providing secretarial, managerial and implementation support and carrying out other responsibilities as assigned by DoP from time to time.

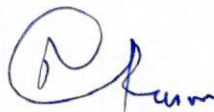
11.3. Detailed constitution, functioning and responsibilities of the PMA will be elaborated in the Scheme Guidelines.

11.4. For carrying out activities related to the implementation of PLI Scheme, PMA would inter-alia be responsible for:-

11.4.1. Appraisal of applications and verification of eligibility for support under the Scheme.

11.4.2. Examination of claims eligible for disbursement of incentive under the Scheme.

11.4.3. Compilation of data regarding progress and performance of the Scheme including Incremental Investment and Incremental Sales of Manufactured goods for companies under the Scheme.



12. Empowered Committee (EC):

12.1 An Empowered Committee (EC) including Secretary Pharmaceuticals, Secretary Chemicals and Petrochemicals, Secretary DPIIT, Secretary Commerce, Secretary Environment and Secretary Health will be formed. This committee may co-opt subject experts as and when required.

12.2. The Empowered Committee will be assisted by a Technical Committee of experts to be constituted by Department of Pharmaceuticals.

12.3. The EC will consider applications, as found eligible by the Project Management Agency under the Scheme, for approval.

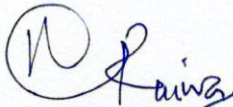
12.4. The EC will consider claims, as examined and recommended by the Project Management Agency, for disbursement as per the laid down procedure and guidelines.

12.5. The EC will conduct a periodic review of eligible companies with respect to their investments, employment generation, production and value addition under the Scheme.

12.6. The EC will also be authorized to carry out any amendments in the Scheme Guidelines.

12.7. Detailed constitution, functioning and responsibilities of the EC will be elaborated in the Scheme Guidelines.


13. The detailed guidelines of the scheme will follow.


Navdeep Rinwa
(Joint Secretary)

ANNEXURE A

List of products identified

S. No.	Name of the product	S. No.	Name of the product
1.	Amoxicillin	28.	Ciprofloxacin
2.	Azithromycin	29.	Losartan
3.	Erythromycin Stearate/ Estolate	30.	Telmisartan
4.	Ceftriaxone	31.	Artesunate
5.	Cefoperazone	32.	Norfloxacin
6.	Cefixime	33.	Ofloxacin
7.	Cephalexin	34.	Metronidazole
8.	Piperacillin Tazobactam	35.	Sulfadiazine
9.	Sulbactam	36.	Levofloxacin
10.	Dexamethasone	37.	Meropenem
11.	Prednisolone	38.	Paracetamol
12.	Metformin	39.	Tinidazole
13.	Gabapentin	40.	Ornidazole
14.	Rifampicin	41.	Ritonavir
15.	Vitamin B1	42.	Diclofenac Sodium
16.	Vitamin B6	43.	Aspirin
17.	Clindamycin Phosphate	44.	Levetiracetam
18.	Clindamycin HCL	45.	Carbidopa
19.	Streptomycin	46.	Levodopa
20.	Neomycin	47.	Carbamazepine
21.	Gentamycin	48.	Oxcarbazepine
22.	Doxycycline	49.	Valsartan
23.	Potassium Clavulanate	50.	Olmesartan
24.	Oxytetracycline	51.	Atorvastatin
25.	Tetracycline	52.	Acyclovir
26.	Clarithromycin	53.	Lopinavir
27.	Betamethasone		



Target segments of critical KSMs/Drug Intermediates and APIs**I. Fermentation Based 04 KSMs/Drug Intermediates and corresponding APIs**

1. Penicillin G/ 6-Amino Penicillanic Acid (6-APA)
2. Cephalosporin C/ 7-Amino Cephalosporanic Acid (7-ACA)
3. Erythromycin Thiocyanate/ TIOC
4. Potassium Clavulanate

II. Fermentation Based 10 Niche KSMs/Drug Intermediates and corresponding APIs

1. Cyclins (Tetracycline, Oxycycline, Doxycycline)
2. Aminoglycosides (Gentamycin)
3. Aminoglycosides (Neomycin)
4. Aminoglycosides (Streptomycin)
5. Steroids (Betamethasone)
6. Steroids (Dexamethasone)
7. Steroids (Prednisolone)
8. Anti TB (Rifampicin)
9. Vitamins and Nutraceuticals (Vitamin B6)
10. Vitamins and Nutraceuticals (Vitamin B1)

III. Chemical Synthesis Based 04 KSMs/Drug Intermediates and corresponding APIs (with backward integration)

1. Dicyandiamide (DCDA)
2. Para-aminophenol
3. 2-Methyl-5Nitro-Imidazole (2-MNI) including Imidazoles.
4. 1,1 Cyclohexane Diacetic Acid (CDA)

IV. Other Chemical Synthesis Based 23 KSMs/Drug Intermediates and corresponding APIs (with backward integration)

1.	Levofloxacin	13	Lopinavir
2.	Sulfadiazine	14	Ritonavir
3.	Ciprofloxacin	15	Oxcarbazepine
4.	Ofloxacin	16	Carbamazepine
5.	Norfloxacin	17	Levodopa
6.	Artesunate	18	Carbidopa
7.	Telmisartan	19	Levetiracetam
8.	Losartan	20	Aspirin
9.	Valsartan	21	Diclofenac Sodium
10.	Olmesartan	22	Tinidazole
11.	Atorvastatin	23	Ornidazole
12.	Acyclovir		

