

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

New Delhi, dated the 2nd June, 2020

Subject:- Scheme for Promotion of Bulk Drug Parks.

1. Background

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

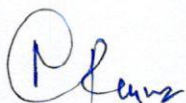
1.2. Medicines play a major role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supplies can have significant adverse impact on Drug Security, which is also linked to the overall economy of 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 Active Pharmaceutical Ingredients and our ability to upscale the manufacturing to meet emergencies. India could only become the true pharmacy of the world by ensuring the uninterrupted supply.

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 13 in terms of value. However, despite these achievements, India is significantly dependent on import of basic raw materials, viz., Bulk Drugs that are used to produce the Finished Dosage Formulations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during 2018-19. India imports bulk drugs largely for economic considerations.

1.5. With a view to increase the competitiveness, easy access to standard testing and infrastructure facilities and value addition in the domestic bulk drug industry, a sub-scheme called "*Assistance to Bulk Drug Industry for Common facility Centre*" under the umbrella scheme of "Development of Pharmaceutical Industry", was formulated in the year 2018. Under the said sub-scheme, financial assistance was envisaged to be provided for creation of identified common infrastructure facilities in a bulk drug park promoted by a State Government. The scheme took off slowly as the maximum limit of financial support was limited only to Rs. 100 Crore per park with a total outlay for the sub scheme of Rs. 200 Crore.

1.6. Since the creation of common facilities required large investment, the existing scheme has been revised to provide adequate funds to the proposed bulk drug parks.



This would bring down the manufacturing cost significantly to create a robust ecosystem for bulk drugs manufacturing in the country.

2. **Objective**

2.1. Set up Bulk Drug Parks for ensuring drug security and reducing import dependence on APIs. Strengthening the existing infrastructure facilities in order to make Indian Bulk Drug Industry a global leader.

2.2. Easy access to standard testing and infrastructure facilities and value addition in the domestic Bulk Drug Industry through creation of world class Common Infrastructure Facilities for increased competitiveness.

2.3. To help industry meet the requirements of standards of environment at a reduced cost through innovative methods of common Waste Management System.

2.4. Exploit the benefits arising due to optimization of resources and economies of scale.

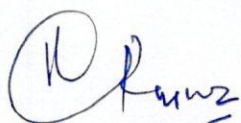
3. **Financial Assistance:** The scheme proposes to provide grants-in-aid to three (3) Bulk Drug Parks with a maximum limit of Rs. 1,000 Crore per Bulk Drug Park or 70% of the project cost of Common Infrastructure Facilities, whichever is less. In case of hilly states and North East Region, the grant-in-aid would be Rs. 1000 Crore per Bulk Drug Park or 90% of the project cost of Common Infrastructure Facilities, whichever is less. Grant-in-Aid from Government of India will not be utilized towards land and building components of the project.

4. **Scope and Coverage:** Assistance under the Scheme will be admissible for creation of Common Infrastructure Facilities by State Governments in Bulk Drug Parks.

5. **Indicated Common Infrastructure Facilities:** The assistance under the proposed scheme will be admissible for creation of Common Infrastructure Facilities such as Solvent recovery and Distillation Plant, Central Effluent Treatment Plants, Captive Power Plants, Steam and Cooling systems, Incubation facilities, Common Logistic facilities, Advance Common Testing Centre, Regulatory awareness facility Centre, Emergency Response Centre etc.

6. **Incentive Outlay:** The incentive outlay is Rs. 3,000 Crore for providing financial assistance for construction of Common Infrastructure Facilities in 3 Bulk Drug Parks with a maximum limit of Rs. 1,000.

7. **Tenure of the Scheme:** The scheme shall be open during the period 2020-2021 to 2024-2025.



8. Implementation of the Scheme

8.1. The Scheme would be implemented through a one-time grant-in-aid to be released in various phases for creation of Common Infrastructure Facilities in Bulk Drug Park to a State Implementing Agency (SIA).

8.2. The Scheme Steering Committee (SSC) in the Department of Pharmaceuticals (DoP) shall approve the project components and funding thereof depending upon the merits of the proposal.

9. The detailed guidelines of the scheme will follow.



Navdeep Rinwa
(Joint Secretary)