

NOTIFICATIONNew Delhi, the 21st July, 2020**Subject:- Scheme for Promotion of Bulk Drug Parks.****No. 31026/16/2020-Policy.—1. Background**

- 1.1. 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.
- 1.2. 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. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during 2018-19.
- 1.3. Future growth of pharmaceutical sector is contingent upon our ability to ensure uninterrupted supply of quality bulk drugs and our capacity to upscale their manufacturing during emergency situations. Self-reliance in manufacturing of bulk drugs is, therefore, highly desirable.
- 1.4. With a view to significantly bring down the manufacturing cost of bulk drugs and thereby increase the competitiveness of the domestic bulk drug industry by providing easy access to standard testing & infrastructure facilities, a scheme called “Promotion of Bulk Drug Parks” has been approved by the Government of India on 20th March 2020.

2. Objective

- 2.1. To promote setting up of bulk drug parks in the country for providing easy access to world class common infrastructure facilities to bulk drug units located in the parks in order to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry.
 - 2.2. To help industry meet the standards of environment at a reduced cost through innovative methods of common waste management system.
 - 2.3. To exploit the benefits arising due to optimization of resources and economies of scale.
3. **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.
 4. **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 Rs. 1000 crore.
 5. **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.
 6. **Financial outlay:** The total financial outlay of the Scheme is Rs. 3,000 crore.
 7. **Tenure of the Scheme:** The tenure of the Scheme is from FY 2020-2021 to FY 2024-2025.
 8. **State Implementing Agency**
 - 8.1. A Bulk Drug Park project selected under the Scheme will be implemented by a State Implementing Agency (SIA).

- 8.2. SIA shall be a legal entity set up by the concerned State government for the purpose of implementing the Bulk Drug Park project.

9. Scheme Steering Committee

- 9.1. The proposals under the scheme will be approved by the Scheme Steering Committee (SSC) constituted by Department of Pharmaceuticals (DoP).

- 9.2. The composition of the SSC is as follows:

Secretary, DoP	-	Chairperson
Financial Adviser, DoP	-	Member
Joint Secretary, Ministry of Environment, Forest and Climate Change	-	Member
Joint Secretary, Department for Promotion of Industry - and Internal Trade	-	Member
Joint Secretary, Department of Health and Family Welfare -	-	Member
DCGI, Central Drugs Standard Control Organisation	-	Member
Joint Secretary (Policy), DoP	-	Convenor

The SSC may invite representatives of Industry Associations, R&D Institutions and other Government / Private sector expert organizations as special invitees as may be necessary from time to time.

- 9.3. The SSC shall take all decisions required for successful implementation of the scheme, including any modifications if required.

- 10.** The detailed guidelines of the scheme will be uploaded on the website of the Department.

- 11.** This Notification supersedes the earlier Notification of the Department of Pharmaceuticals issued on this subject vide no 31026/16/2020-Policy dated 2nd June, 2020.

NAVDEEP RINWA, Jt. Secy.