

Scheme for Cluster Development Programme for Pharma Sector (CDP-PS)

1. Introduction

The vision of the Department of Pharmaceutical (DoP), Ministry of Chemicals & Fertilizers is to catalyze and encourage quality, productivity and innovation in pharmaceutical sector and to enable the Indian pharmaceutical industry to play a leading role in a competitive global market. For this, world class quality manufacturing facilities with high level of productivity with innovative capabilities are required. However, these are on one hand very capital intensive and cannot be established and opened by Pharma Manufacturing Units especially the SMEs at their own due to financial constraints while on the other hand global level technical expertise is an adverse handicap.

Cluster based approach is increasingly being recognized as an effective and sustainable strategy for competitive enhancement of Pharmaceutical Industry. Such an approach, which leverages the geographical proximity of the enterprises on 'collaborating while competing' principle, is participatory and cost effective. As it provides critical mass for customization of interventions, the DoP seeks to implement **Cluster Development Programme for Pharma Sector (CDP-PS)** to enhance Quality, Productivity & Innovative capabilities of the SME Pharma sector in the country.

2. Objective

- i. Increase the competitiveness, easy access to standard testing facilities and value addition in the domestic pharma industry especially to SMEs through creation of common world class facilities.

- ii. Strengthening the existing infrastructure facilities in order to make Indian Pharma industry a global leader in pharma exports.
- iii. Reducing the cost of production by 20% in the clusters leading to better availability and affordability medicines in domestic market.
- iv. To help industry meet the requirements of standards of environment at a reduced cost through innovative methods of common waste management system.
- v. Exploit the benefits arising due to optimization of resources and economies of scale.
- vi. To provide information of latest global developments in the sector related to regulations, IPR issues, new products, new markets etc.

3. The Scheme

- i. The Scheme termed as '**Cluster Development Programme for Pharma Sector' (CDP-PS)**, is proposed as a Central Sector Scheme for the remaining years of the 12th Plan and also to continue in the next Five Year Plan.
- ii. The total size of the scheme is proposed as Rs.125 Crores for CDP-PS for 12th Five Year Plan.
- iii. The Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant –in – aid to be released in various phases for creation of identified infrastructure and common facilities to a Special Purpose Vehicles (SPVs) set up for the purpose. The details of SPV are in Section 8.

- iv. The scheme is for setting up of new cluster as well as Upgradation of existing cluster. However, the purpose of the grant is for activities of common facilities.
- v. The various aspects and the outcomes of the Scheme will be reviewed after three years from the date of its starting.

4. Scope and Coverage

Assistance under the Scheme will be admissible for creation of common facilities:

4.1 Common Facilities

Common Facilities under the CDP-PS will consist of creation of tangible "assets" as Common Facility Centers (CFCs). Some of the indicative activities under the Common facilities are:

- i. Common Testing Facilities
- ii. Training Centre
- iii. R&D Centres
- iv. Effluent Treatment Plant
- v. Common Logistics Centre

The above list of common facilities is illustrative and each cluster could have its own specific requirements based on the nature of units being set up and the products proposed to be manufactured. The Scheme Steering Committee (SSC) shall approve the project components and funding thereof depending upon the merits of the proposal.

- i. The land and building for CFC shall be provided by SPV/State Government concerned as per cost indicated. In case existing land

and building is provided by stakeholders, the cost of land and building will be decided on the basis of valuation report prepared by an approved agency of Central/State Govt. Departments/ FIs /Public Sector Banks and the cost of land and building may be taken towards contribution for the project.

- ii. The CFC may be utilized by the SPV members and as also others in the cluster.
- iii. The CFC should be operationalised within two years from the date of final approval, unless extended with the approval of Scheme Steering Committee (SSC).
- iv. Escalation in the cost of project over and above the sanctioned amount, due to any reason, will be borne by the SPV / State Government. The Central Government shall not accept any financial liability arising out of operation of any CFC.
- v. User charges for services of CFC shall be on differential rate basis, lower fee for small units and higher fee for medium ones. However, the user charges will be graded in such a manner that average charges will be close to prevailing market prices, as decided by the Governing Council of the SPV. The SPV members would be given reasonable preference in user charges.
- vi. A Tripartite Agreement shall be entered into among the GOI, the State Government concerned and the SPV for CFC projects.

5. Eligibility

5.1 Eligibility for Common Facility Centers:

i. Special Purpose Vehicle:

It is necessary to form an SPV prior to setting up of and running the proposed CFC. An SPV is a clear legal entity (Cooperative Society, Registered Society, Trust or a Company) with members located within a radius of 10-15 km. The SPV should have a provision for enrolling new members to enable prospective entrepreneurs in the cluster to utilize the facility should be provided. In addition to the contributing members of the SPV, the organizers should obtain written commitments from 'users' of the proposed facilities so that its benefits can be further enlarged. There should be a minimum of 10 units serving as members of the Special Purpose Vehicle (SPV). There is no ceiling on the maximum number of members.

The scope of the Grant in-aid shall only be for the development of common facilities to be held with the SPV and shall not be available to production units, if any, owned by SPV.

ii. Detailed Project Reports (DPR)

A Detailed Project Report (DPR) has to be prepared by the SPV with 50% contribution from the Department (para 5.2.ii) and submitted to the Department as the first and foremost activity for assistance under this category. The DPR should have details of all the business processes of the cluster units viz. manufacturing process, technology, marketing, quality control, testing, purchase, outsourcing, etc. to identify impediments and bottlenecks; and to draw action plan for enhancing competitiveness of the units of the cluster and to position the cluster on a self sustaining trajectory of growth. DPR should focus on enhanced competitiveness, technology improvement, adoption of best manufacturing practices, marketing of products, employment

generation, etc. There has to be direct linkages between the impediments/bottlenecks identified and the measures recommended for improvement in the DPR.

6. Financial Assistance

- i. Maximum limit for the grant in aid under this category would be Rs Rs 20.00 crore per cluster or 70% of the cost of project whichever is less. Gol grant will be 90% for CFCs for difficult and backward regions. The cost of project includes cost of Land, building, pre-operative expenses like preparation of DPR, administrative and management support expenses including the salary of CEO, engineers, other experts and staff during the project implementation period, preliminary expenses, machinery & equipment, miscellaneous fixed assets and other support infrastructure such as water supply, electricity and margin money for working capital.
- ii. As the first step is to submit a DPR, the SPV may approach the Department for contribution towards preparation of DPR. The Department will consider the proposal on 50:50 basis i.e. 50% by the Government and 50% by the SPV subject to a maximum Government contribution of Rs. 5.00 lakhs. 50% of the Government contribution i.e. Rs. 2.50 lakhs will be released after the approval against indemnity bond and other documentary requirements the balance 50% (Rs. 2.50 lakhs) will be released after the report is accepted. If the project is not approved, the funding by the Government (Rs. 2.50 lakhs) will go as a grant out of the Programme. In case, the project is approved, the payment released for DPR will be adjusted in the overall Government contribution.

- iii. Assistance for Administrative and other management support of SPV including the salary of CEO for the project implementation period shall not exceed 5 % of the Grant in –aid.
- iv. Assistance for engaging engineers and other experts for execution of civil works shall not exceed 5 % of the Grant in Aid.
- v. Contribution by the SPV / State Government or the beneficiaries' share should be made upfront. Necessary infrastructure like land, access road, water and power supply, etc. must be in place or substantial progress should have been made in this regard before Gol assistance is released. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds will also be necessary before release of Gol assistance.
- vi. Funds will be released in installments depending upon the implementation plan, requirements of funds and as approved by the Scheme Steering Committee (SSC)

6.2.1 Other Requirements of Common facility Centers

In addition to foregoing, any proposal prepared under the scheme should meet the following:

- i. It should necessarily have a testing laboratory. If there is no proposal for the testing laboratory, the reason for not including the same must be spelt out clearly.
- ii. User charges for services of CFCs shall be on differential rate basis, lower fee for small units and higher fee for medium ones. However,

the user charges will be graded in such a manner that average charges will be close to prevailing market prices, as decided by the Governing Council of the SPV.

- iii. It shall be the responsibility of the SPV to bring in land as its contribution;
- iv. SPVs may dovetail funds from other sources as well for the project, provided there is no duplication of funding for the same component/ intervention. However, in cases of such dovetailing, it shall be ensured that the contribution of the participating units of SPV is at least 10% of the overall project cost.

7. Time Frame for CFC Project Implementation

The time frame for implementation of an approved project would be 2 years from the date of approval of the projects.

8. Special Purpose Vehicle (SPV)

- i. The project will be implemented through a Special Purpose Vehicle (SPV), a non-profit making company registered under section 25 of the Companies Act. It will have the representatives from cluster members, financial institutions, State & Central Government and R&D organisation. The SPV shall have full operational autonomy to develop, operate and maintain the infrastructure.
- ii. SPV should represent the cluster as a whole and should have a minimum of 10 manufacturer enterprises of pharma producers as its shareholders.
- iii. The share of the cluster beneficiaries should be as high as possible but not less than 10 per cent of the total cost of CFC. State Government's/other stakeholders contribution will be considered as

gap filling funds. All the participating units should be independent in terms of their financial stakes and management. No single unit will hold more than 10 per cent in the equity capital (or equivalent capital contribution) of the SPV.

- iv. Large mother manufacturing firms (whether in the public or private sector), other major buyers of the cluster MSE products, commercial machinery suppliers, raw material suppliers and business development service (BDS) providers can also be members of SPV, provided management of SPV remains clearly with the intended beneficiary SPV. The SPV may also raise loans from banks to take care of any shortfall, expansion, etc. on the condition that the plant and machinery in the CFC purchased with Government assistance will not be hypothecated and the first right thereto will rest with the Government.
- v. Pharma enterprises shall hold at least 51% equity of the SPV and remaining may be held by any Government agency, Financial Institution/Bank, strategic partners etc.
- vi. The shareholding/member enterprises taking/holding stake in the SPV shall be legally independent entities without any related party relationship with each other as described under Accounting Standard (AS) 18 of the Companies (Accounting Standard) Rules, 2006.
- vii. No dividends are to be declared by the SPV-rather the profits are to be ploughed back into the SPV.
- viii. The SPV will have quarterly meetings and will prepare Annual Report and Audited Account to be laid on the Table of Both Houses of Parliament Annually.

- ix. There shall be one nominee of the DoP and one nominee of Project Management Consultant(PMC) on the Board of Directors of the SPV till completion of the project.
- x. Although SPV/Project Implementing Agency would fulfill the requirements as decided by SSC to avoid any conflict of interest and smooth implementation and operation of the project, however the broad activities and roles played by SPV would be the following:
 - a. Prepare the Detailed Project Report covering the technical, financial, institutional and O&M aspects of the projects.
 - b. Raise balance amount of Project cost.
 - c. Obtaining any statutory approvals/ clearances including release of funds.
 - d. Recruit suitable functional professionals in order to ensure that the project is executed smoothly.
 - e. Implement various interventions as outlined and approved in DPR.
 - f. O&M of assets created under the project by way of user services.
 - g. Furnish regular progress reports to DoP.

9. Project Management Consultant (PMC)

- i. The Department of Pharmaceuticals would engage the services of an agency that has experience in developing, financing and executing the cluster development/Upgradation projects from the stage of conceptualization to commissioning. PMC, a bridge between the DoP and the SPV, would act as a catalyst in

expeditious implementation of the projects in a systematic, professional and transparent manner. The period of consultancy will depend on the requirement of individual cluster as approved by the Department of Pharmaceuticals.

- ii. The PMC will report directly to the DoP and shall have the following responsibilities:
 - a. Sensitisation of the industry/ potential beneficiaries on the scheme and its benefits and also guiding the to be formed SPV, in drafting its Memorandum and Article of Association.
 - b. Formulating evaluation criteria for selection of Projects based on the received proposals
 - c. Appraisal of the DPRs indicating financial viability, commercial sustainability and socio-economic impact for according final approval to the projects.
 - d. Assist DoP in formulating a suitable strategy for implementation of the scheme.
 - e. Assist the DoP in periodical monitoring the progress of the projects, and disbursement of funds to the SPVs and their utilisation.
 - f. Assist the SPVs in liasioning with the State Government agencies for land and other support infrastructure.
 - g. Assist the SPVs in selection of agencies/ experts for various services such as capacity building, business development, technical, engineering, etc.;
 - h. Assist the SPV in developing suitable O&M framework for making it more effective and enforceable so as to ensure that there is no conflict of interest. ;
 - m. Provide other need based advisory services to the SPV in effective implementation of the scheme;

- iii. PMC will be selected by the Department on the basis of open bid system. The fee to the PMC would be separate from the grant being given to projects and will be met from "New Schemes" Head.

10. Role of State Governments:

The State Government is envisaged to play a pro-active role in the following areas:

- (a) Providing the necessary assistance for external/ access infrastructure as roads, Power, Water supply etc.
- (b) Providing requisite land to the project, wherever needed, in appropriate mode
- (c) Undertaking equity stake in the SPV, where there is a possibility of development of projects together with the SPV.
- (d) Providing flexible and conducive environment and consider special facilities like exemption of stamp duty etc. for the SPV/ units
- (e) Dovetailing assistance available under related schemes for overall effectiveness and viability of the projects.
- (f) Providing necessary project related clearances on expeditiously.

11. Implementation Framework

11.1 Scheme Steering Committee (SSC)

The Department of Pharmaceuticals (DoP) will be the coordinating department for providing overall policy, coordination and management support to the Scheme. The proposals under the scheme will be considered for approval by the **Scheme Steering Committee (SSC)** of the CDP-PS.

The composition of the Steering Committee will be as follows:

- i. Secretary (DoP) - Chairman
- ii. Financial Adviser (C& F)
- iii. Additional Secretary & Development Commissioner (MSME)
- iv. Adviser, Planning Commission
- v. Joint Secretary, DoP
- vi. Joint Secretary, DIPP
- vii. Representative(s) of Pharma Industry Association(s) / Special invitees/ financial institutions/ programme management consultant.
- viii. The SSC may co-opt representatives of any industry associations, R&D institutions and other private sector expert organizations as members or special invitees.

12. Project Approval

The SSC shall approve the projects and also monitor their implementation. There would be two-stage process for approval of the projects viz. 'In-principle' approval and final approval.

a. In-principle approval:

'In-principle' approval for a project will be accorded by the SSC based on preliminary proposal submitted by the PMC/ Industry Association/ groups of entrepreneurs covering the major features of the proposed project and availability of land. Such 'in-principle' approval will be valid for a period of 6 months from the date of approval. Before that, it is expected that the project would be ready for final approval. In case

final approval is not accorded to the project within 6 months, 'in-principle' approval will automatically lapse, unless it is specifically extended by the SSC.

b. Final Approval

A project will be accorded final approval by the SSC if the following conditions are fulfilled:

- i. Establishment of project specific SPV;
- ii. Execution of shareholders agreement and other related agreements between the SPV and the members;
- iii. Preparation of DPR by SPV and its appraisal by PMC;
- iv. Procurement of requisite land by the SPV;
- v. Establishment of project specific Trust and Retention Account (TRA), with Schedule Commercial Banks by the SPV. DoP would credit funds into this account;
- vi. Tying up of sources of funds for the balance amount.

13 Guidelines for Release of Funds

Based on the DPR and the nature of the project, detailed guidelines in respect of implementation of the project and subsequently release of funds by the Department will be prepared by the PMC and approved by the Scheme Steering Committee (SSC).

- i. However, broadly following schedule will be adopted for release of share of funds of DoP to the SPV:
 - a. 20% as 1st installment as mobilization advance against an Indemnity Bond, on Final Approval of the project by SSC;

- b. 30% as 2nd installment against the production of Bills ; and
 - c. 30% as 3rd installment against the production of Bills.
 - d.10% as final installment
- ii. 2nd Installment would be released after the utilisation of at least 60% of the 1st installment and after the proportionate expenditure has been incurred by the SPV;
 - iii. 3rd and final installment would be released after 100% utilisation of 1st installment and at least 60% utilization of 2nd installments and after the proportionate expenditure has been incurred by the SPV;
 - iv. Final installment would be released after SPV has mobilized and spent its entire share in proportion to grant
 - v. The SPVs shall submit the Utilisation Certificate (UC) for the amounts utilized as per the format in accordance with GFR 19A;
 - vi. Accounts of SPV shall be subject to audit by the Comptroller & Auditor General of India.

14. Maintenance /Ownership of Assets

- i. SPV shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/ users;
- ii. SPV shall ensure that the services of the facilities created under the scheme are extended to the cluster in general, in addition to the member enterprises;

- iii. The Assets acquired by the SPV out of government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.

- v. A register of permanent and semi permanent assets acquired wholly or mainly out of the funds provided by GOI should be maintained in the Form GFR 19.

- vi. If for any reason SPV is liquidated, Government of India will have the first right to recover the grant funds provided by it. The assets created with such grant funds and any unutilized fund shall be vested with the Central Government. The Memorandum of Association & Articles of Association of the SPV with the Government shall incorporate this condition.
