25.05.10

## **CONCEPT PAPER**

#### On

## Cluster Development Programme for Pharma Sector (CDP-PS) for World Class Quality, Productivity & Innovation –Views/Comments/Suggestions Requested

## Need

The vision of the Department of Pharmaceutical (DoP), Ministry of Chemicals & Fertilizers, Government of India 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 and innovative capabilities are required. However, these are on one hand very capital intensive and cannot be established and opened by Pharma SMEs at their own, due to financial constraints, and on the other global level technical expertise is an adverse handicap. It is for this reason that the DoP proposes to formulate Cluster Proforma Pharma (CDP-PS) Development for Sector to enhance Quality, Productivity & Innovative capabilities of the SME Pharma sector in the country.

## 2. Proposal

Development of Pharma industry through the proposed Cluster Development Programme of the Ministry of MSME aims to help achieve better quality and higher productivity for all round growth of the pharma industry in the country.

The Scheme proposes adoption of cluster development approach as a key strategy for enhancing productivity and competitiveness as well as capacity building of Small and Medium Enterprises (SMEs) located in clusters. Such clusters presently exist in Baddi (HP), Hardwar (Uttarakhand) and Gurgaon (Haryana) in the north, Pattancheru, Pashmalyram and Khazipalli (in A.P), Alandur and Ambattur (both in TN) in the South, Thane, Nashik, Aurangabad (all in Maharashtra), Vadodra and Ahmedabad in Gujarat in the West and Goa/Sikkim in other special areas. In particular, the Scheme proposes to support the following common facilities on a need-based basis:

To set up Formulation Development Facilities

- i. To set up GLP for calibrating and validating important equipments. This includes testing facilities such as Analytical Lab, Toxicology Centre, Process & Product Validation Laboratory, Raw Material Testing, Standardization laboratory etc which will enable better Quality Assurance & Control
- ii. To set up common incinerator
- iii. To set up common ETP (Effluent Treatment Plant)
- iv. To set up training centre for imparting training for appropriate documentation for Pharma Sector.
- v. To support the first level processing facilities such as cleaning, drying, sorting, storing, extracting, packaging etc.
- vi. Facilities for Tableting, Capsulation, Packaging and Labeling
- vii. Standardization of raw materials and finished products
- viii. Development of references and standards
- ix. Adoption of new technologies and processes
- x. Application of ERP and other IT tools
- xi. Assistance for ISO, WHO GMP, GLP, US FDA, EU GMP, Australian TGA and other standards and Compliances
- xii. Development of DMF<sup>1</sup> for the purpose of registration with regulatory bodies overseas
- xiii. Studies/ surveys
- xiv. Preparation of DPRs
- xv. Sensitization/ Awareness creation/ Skill development at Entrepreneurial Level, Managerial Level and Worker Level
- xvi. Hiring of Cluster Development Executives (CDEs)

<sup>&</sup>lt;sup>1</sup> Drug Master File

## 3. Strategy and Approach

Given the diverse nature of the Pharma Sector within the country both in terms of geographical location and sectoral composition, the **CDP-PS** scheme aims at addressing the need of the Pharma Sector, through well defined clusters and geographical areas. This will enable achieving the economies of scale in terms of deployment of resources as well as focusing on the specific needs of the sector.

## 4. Diagnostic Study for every Cluster

Specific needs of the cluster regarding technology up-gradation, lean manufacturing technology bench marking (International and national), certification system (WHO/other International), Productivity & Quality development requirements would be done through a Detailed Diagnostic Report (DDR). This DDR would be funded by DoP with wide participation of Industry concerned. The DDR will detail Implementation Action Points.

## 5. Soft Interventions:

Soft activities under the programme would consist of activities which lead to creation of general awareness, counselling, motivation and trust building, exposure visits, market development including exports, participation in seminars, workshops and training programmes on technology up-gradation, quality control & competitiveness, etc. These interventions would bring about improvement in the existing working of the Pharma Sector in the cluster.

## 6. Hard Intervention/Common Facility Centres (CFCs):

The CDP-PS intends to intervene in the existing clusters for purposes of providing one or all of the interventions as listed in para-2 of this Concept Paper. Purposes of interventions could include setting up new Common Facility Centres (CFC) in new cluster to be developed or intervention in the existing cluster for one or all of the following:

- i. Setting up GLP facility;
- ii. HRD and Training Programmes for the objective of CFCs;
- iii. Intervention for environment management;
- iv. Intervention for hazard management;

- v. Intervention for quality control, improved productivity and competitiveness;
- vi. Any other intervention as listed in the objectives of CDP;

Creation of tangible "assets" like GLP, ETP, R & D Centre, Incinerator, Training Centre, Testing Facility, Effluent Treatment Plant, Training Centre, Raw Material Bank, or any other such need based facility would constitute CFCs.

## 7. Cluster Based Project for Development of Medical Devices.

It may please be noted here that the example of cluster development for medical devices given hereunder is just for illustrative purpose.

## 7.1 Medical Devices Project in Gujarat : Current Status

- i. The Medical Devices & Manufacturing Industry (MDMI) in India is largely dependent on imports with limited manufacturing facilities in the country and the domestic production is restricted to only low technology products. This has resulted in high cost of treatment, which can be reduced considerably, if the products are manufactured in the country.
- ii. Over the years, limited availability of skilled manpower and poor access to high end-technology has restricted the growth of the sector. There are about 150 medical devices and equipment units supported by 100 raw material/component suppliers in Gujarat largely scattered.
- iii. The sub-sectors with significant contribution include:
  - Orthopedic Implants
  - Ophthalmic Implants / Products
  - Diagnostic Products
  - Cardiology Implants / Products
  - Surgical Instruments /Accessories
  - Non-woven and medical textiles
  - Dental Implants / Products

## 7.2. Gap Analysis in Medical Devices

Based on the gap analysis undertaken, the following impediments / growth

constraints, as faced by the industry, have been noted:

## i. Lack of access to Business Development Services (BD S) & information on Quality related requirements:

To attain quality certifications like ISO, CE Mark, WHO-GMP SMEs often lack the required information, appropriate technical training, knowledge of desired plant layout/machinery requirements, and are not able to locate affordable BDS providers to organize such activities

## ii. Lack of adequate infrastructure facilities

Most of the SMEs are scattered in the country and these Units operate either in small rented / owned premises with minimum facilities like testing laboratory, training centers for skilled manpower, etc.

## iii. Lack of focus on R&D and innovation:

Medical devices sector in general, and SMEs within the sector in particular, have no focus on R&D and new product development. Hence, the industry continues to be at a nascent stage and is dominated by imports.

# iv. Lack of Product Knowledge Dissemination & Access to Information:

Due to inadequate information about the industry and regulatory framework limitations, the sector is not able to motivate new entrepreneurs to enter medical device manufacturing. Most of the SMEs find it convenient to import and supply to the consumers rather than getting into manufacturing.

## 7.3 Measures Proposed

In view of the above impediments to growth, interventions are being proposed at policy level as well as industry level

## (i) Policy Level:

Medical Devices / medical equipments may be added as an independent definition instead of being included in the overall definition of drugs and there is a need for separate provisions for the regulation of Medical Devices, instrument, apparatus, appliance, material etc.

# (ii) Setting up of Greenfield Medical Device and Equipment Park having state-of-the-art infrastructure and facilities

## (iii) Capacity Building Facilitation

## 7.4. Implementation Framework

(a) The Department of Pharmaceutical (DoP) would collaborate with State
 Governments (or its designated agency) to set up a Greenfield Medical
 Devices Park;

(b) The State Government(s) are expected to provided land during Phase-I of the development, expandable in a phased manner for setting up the Greenfield Medical Devices Park including the Common Facilities Centre at reasonable cost. The State Government would provide the land for Common Facilities Centre (approx 5 Acres) free of cost to DoP/agency appointed by it.

(c) DoP and State Government or its designated agencies would jointly do the screening of the entrepreneurs willing to set up Units in the Park.

(d) The Common Facility Centre would preferably be set up on a Public Private Partnership mode in an appropriate manner with the predetermined revenue sharing mechanism and the members of the Park would use the same on 'use and pay' basis.

## 7.5. Scale of Assistance

The proposed Medical Devices Cluster would benefit more than 100 industries situated in the region. The outer limit of the grant to be sanctioned by the GOI will be 70% of the cost of the project subject to the maximum of Rs. 15.00 Crores. A copy of CDP of the Ministry of MSME is annexed.

8. Suggestions, comments and views are invited from various SME Pharma Units/Associations on Pharma Clusters as exemplified in Para 2 of this Concept Paper. These suggestions should be limited to the specific aspect of the above CDP-PS Scheme. It requested that these suggestions may be sent to Dr. Ashok Vishandass, Dy. Director General (email: <u>vishandass@nic.in</u>) by 30<sup>th</sup> June, 2010 at the latest to enable DoP to be guided by them for betterment of the Pharma Industry.

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#### <u>Modified Guidelines of</u> Micro and Small Enterprises - Cluster Development Programme (MSE-CDP)

#### Background

The Ministry of Micro, Small and Medium Enterprises (MSME), Government of India (Gol) has adopted the cluster development approach as a key strategy for enhancing the productivity and competitiveness as well as capacity building of Micro and Small Enterprises (MSEs) and their collectives in the country. A cluster is a group of enterprises located within an identifiable and as far as practicable, contiguous area and producing same/similar products/services. The essential characteristics of enterprises in a cluster are (a) Similarity or complementarity in the methods of production, quality

control and testing, energy consumption, pollution control, etc (b) Similar level of technology and marketing strategies/practices (c) Channels for communication among the members of the cluster (d) Common challenges and opportunities.

- 2 In October 2007, the erstwhile cluster development scheme' Small Industries Cluster Development Programme (SICDP), was renamed as 'Micro and Small Enterprises Cluster Development Programme (MSE-CDP). It was also decided that the 'Integrated Infrastructural Development (JID), Scheme shall be subsumed in MSECDP for providing developed sites for new enterprises and upgradation of existing industrial infrastructure. A comprehensive MSE-CDP is being administered by the office of Development Commissioner (MSME), the Ministry of MSME.
- 3 These guidelines for the Micro and Small Enterprises Cluster Development Programme (MSE-CDP) are issued in supersession of the previous guidelines relating to SICDP and IID schemes and encompass, inter-alia, the procedure and funding pattern for admissible activities, namely:-
- i. Diagnostic Study Reports: To map the business processes in the cluster and propose remedial measures, with a validated action plan.
- ii. Soft Interventions: Technical assistance, capacity building, exposure visits, market development, trust building, etc for the cluster units.
- iii. Detailed Project Report: To prepare a technical feasible and financially viable project report for setting up of a common facility center for cluster of MSE units and/or infrastructure development project for new industrial estate/ area or for upgradation of infrastructure in existing industrial estate/ areal cluster.
- iv. Hard Intervention/Common Facility Centers (CFCs): Creation of tangible "assets" like Testing Facility, Design Centre, Production Centre, Effluent Treatment Plant, Training Centre, R&D Centre, Raw Material Bank/Sales Depot, Product Display Centre, Information Centre, any other need based facility.
- v. Infrastructure Development: Development of land, provision of water supply, drainage, Power distribution, non- conventional sources of Energy for common captive use, construction of roads, common facilities such as First Aid Centre, Canteen, other need based infrastructural facilities in new industrial (multi-product) areas/estates or existing industrial areas/estates/clusters. Government of India

The projects sanctioned under erstwhile SICDP (renamed MSE-CDP) and Integrated Infrastructural Development (IID) schemes will also be eligible for financial support issued under the scheme as per earlier approvals.

- 4 Objectives of the Scheme
  - i. To support the sustainability and growth of MSEs by addressing common issues such as improvement of technology, skills and quality, market access, access to capital, etc.
  - ii. To build capacity of MSEs for common supportive action through formation of self help groups, consortia, upgradation of associations, etc.
  - III. To create/upgrade infra structural facilities in the new/existing industrial areas/ clusters of MSEs.
  - w. To set up common facility centres (for testing, training centre, raw materialdepot, effl uent treatment, complementing production processes, etc).
- 5 Strategy and Approach: Given the diverse nature of the MSEs in terms of both geographical location and sectoral composition, the MSE-CDP scheme aims at addressing the needs of the industries, through well defined clusters and geographic al
- areas. This will enable achieving the economies of scale in terms of deployment of resources as well as focusing on the specific needs of similar industries. The capacity building of associations, setting up of special purpose vehicles (SPVs), consortia, etc. which are integral part of the scheme would enable the MSEs to leverage their resources and also to have better access to public resources', linkages to credit and enhance their marketing competitiveness.
- Diagnostic Study: The first and foremost activity in the cluster development process is to conduct a diagnostic study. The objective of conducting diagnostic study in a cluster is to map all the business processes of the cluster units viz. manufacturing processes, technology, marketing, quality control, testing, purchase, outsourcing, etc to find out its strengths, weaknesses, threats and opportunities (SWOT), problems and impediments, suggestions and a well-drawn action plan for enhancing competitiveness of the units of the cluster and to position the cluster on a self sustain ing trajectory of growth. Diagnostic Study Report (DSR) is very important document and the study should be conducted with special attention. The Study 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 problems highlighted in the report and the measures suggested for improvement.
  - a. The DSR should preferably be prepared by the end users and other agencies should only facilitate in preparation of reports. In case the DSR is prepared by other expert agencies other than end users, these reports must be thoroughly discussed with and vetted by the end users and concerned State Government. Such agencies should have relevant expertise in cluster development.
- b. Specific needs of the cluster regarding IPRs, Technology Upgradation, Information and Communication Technologies (ICT), Enterprise Resource Planning (ERP), energy efficiency, lean manufacturing, technology benchmarking (international! national), market potential assessment, skill up-

Gradation/ certification system, design development, comparative study with other clusters, twining of clusters, need to improve safety, health, business literacy, welfare of workforce by the enterprises and their common bodies, social upliftment, etc. should be examined and included in the DSR.

- c. Gol grant of maximum Rs 2.50 lakh will be provided for preparation of DSR for one cluster. For the field organizations of the Ministry of MSME, this financial support will be Rs 1.00 lakh. The cost includes the expenses towards visits to cluster, compilation of data, validation of action plan, hiring of consultant, special studies (if reqd), printing & stationery, etc. 50% of the amount sanctioned will be released after the approval. Balance 50% will be released only after acceptance of report.
- d. DSR for one cluster should be prepared within a period of 3 months, unless extended with the approval of DC(MSME).
- 7 **Soft Interventions:** Soft activities under the programme would consist of activities which lead to creation of general awareness, counseling, motivation and trust building, exposure visits, market development including exports, participation in seminars, workshops and training programmes on technology upgradation, etc. These interventions bring about general attitudinal changes necessary to initiate improvement in the existing style of working of the MSEs in the cluster. It is necessary to prepare a Diagnostic Study Report (DSR) including validated action plan, performance indicatorsllnilestones to evaluate the project, before undertaking Soft Interventions. Activities are undertaken as per approved action plan included in DSR.
  - a. The critical mass in a cluster for effectively realising the demonstrative impact of soft interventions should be maximum but not less than 25 units participating in the cluster development activities. However, for difficult and backward regions and for special entrepreneurs groups having a sizeable presence *ofWomen/SCl* ST/Minorities, the critical mass could be 20.
  - b. Maximum limit for project cost would be Rs 25.00 lakh per cluster. Indicative details of activities are given in Annex 1. Gel grant for the soft interventions will be 75% of the sanctioned amount of the project cost. For NE & Hill States, Clusters with more than 50% (a) micro/ village (b) women owned (c) SC/ST units, the GoI grant will be 90%. The cost of project will be moderated as per *sizel* turnover of the cluster.
  - c. The share of the cluster beneficiaries should be as high as possible but not less than 10 per cent of the total cost of Soft Interventions. State Government! other stakeholders contribution will be considered as gap funding.
  - General State Government!
     General State Government!
     Implementing Agencies that required share of the cost of interventions in the cluster is contributed by the cluster actors and other institutions/stakeholders. Funds will be released in two/three installments depending upon the implementation plan, requirements of funds.

- e. The duration of soft interventions will be maximum 18 months, unless extended with the approval of Steering Committee.
- 8 Detailed Project Report (DPR): A Gol grant of maximum R 5.00 lakh will be provided for preparation of a technical feasible and financially viable project report for setting up of a common facility center for cluster of MSE units and/or infrastructure development project for new industrial estate/ area or for upgradation of existing infrastructure in existing industrial estate/ arealcluster. 50% of the amount sanctioned will be released after the approval. Balance 50% will be released only after acceptance of report.
  - a. The DPR should include financial analysis like internal rate of return, breakeven point, debt-service coverage ratio, sensitivity analysis, etc., using basic templates such as projected profit & bss account, projected balance sheet etc. The indicative format for preparation of DPR is given at Annex 2.
  - b. DPR should be appraised by a bank (if bank financing IS involved)/independent Technical Consultancy Organization/ SIDBI.
- 9 Hard Interventions (setting up of CFCs): Hard Interventions under the programme will consist of creation of tangible "assets" as Common Facility Centers (CFCs) like Common Production/Processing Centre' (for balancing/correcting/improving production line that cannot be undertaken by individual units), Design Centres, Testing Facilities, Training Centre, R&D Centres, Effluent Treatment Plant, Marketing Display/Selling Centre, Common Logistics Centre, Common Raw Material Bank/Sales Depot, etc.
  - a. The Gol grant will be restricted to 70% of the cost of project of maximum Rs 15.00 crore. Gol grant will be 90% for CFCs in NE & Hill States, Clusters with more than 50% (a) micro/ village (b) women owned (c) SC/ST units. The cost of project includes cost of Land (subject to max. of 25% of Project Cost), building, pre-operative expenses, preliminary expenses, machinery & equipment, miscellaneous fixed assets, support infrastructure such as water supply, electricity and margin money for working capital.
  - b. The entire cost of land and building for CFC shall be met by SPY/State Government concerned. 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 IFIs/Public Sector Banks. Cost of land and building may be taken towards contribution for the project. CFC can be set LIp in leased premises. However, the lease should be legally tenable and for a fairly long duration (say 15 years).
  - c. It is necessary to form an SPY prior to setting Lip of and running the proposed CFC. An SPY is a clear legal entity (Cooperative Society, Registered Society, Trust or a Company) with evidence of prior experience of positive collaboration among its members. The SPY should have a character of inclusiveness wherein provision for enrolling new members to enable prospective entrepreneurs in the cluster to utilise the facility should be provided. In addition to the contributing members of the SPY, the organizers

should obtain written commitments from 'users' of the proposed facilities so that its benefits can be further enlarged. Bylaws of SPY should have provisions for *CDEI* CDA and one State Govt official as members of the SPY.

- d. There should be a minimum of 20 MSE cluster units serving as members of the Special Purpose Vehicle (SPV). There is no ceiling on the maximum number of members. In special cases, where considerations of investments, technology or small 'size of the cluster warrant lesser number of units, a minimum of 1 0 MSE units may be considered for the SPY.
- e. 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 contribution will be considered as gap funding. 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 SPY.
- f. 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 will be eligible to contribute up to 49 per cent for SPY, provided management of Spy remains clearly with the intended beneficiary SPV. The SPY may also raise loans from banks to take care of anyshortfall, 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.
- g. Contribution by the SPY *IState* Government or the beneficiaries' share should be made upfront. Necessary infrastructure like knd, building, 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.
- h. The CFC may be utilized by the Spy members and as also others in the cluster.
- I. The CFC should be operations lised within two years from the date of final approval, unless extended with the approval of Steering Committee.
- J. Escalation in the cost of project above the sanctioned amount, due to any reason, will be borne by the SPY / State Government. The Central Government shall not accept any financial liability arising out of operation of any CFC.
- k. User charges for services of CFC shall be close to prevailing market prices, as decided by the Governing Council of the SPY. The Spy members may be given reasonable preference in user charges.

- The CFC with cost higher than Rs 15,00 crore may also be considered under MSE-CDP. However, the Gol grant will be calculated with project cost ceiling of Rs 15.00 crore.
- m. Funds will be released in, two/three installments (after final approval) depending upon the implementation plan, requirements of funds.
- n. A Tripartite Agreement among the Gal, the State Government concerned and the SPY shall be signed for CFC projects. The format of the agreement is given at Annex 3.
- o. Exhibition Centres by Associations of Women Entrepreneurs: The Gol assistance shall also be available to Associations of Women Entrepreneurs for establishing exhibition centres at central places for display and sale of products of women owned micro and small enterprises @ 40% of the project cost. The Gol contribution will be towards furnishings, furniture, fittings, items of permanent display, miscellaneous assets like generators, etc.
- 10 Infrastructure Development: Infrastructure Development projects under the scheme will consist of projects for infrastructural facilities like power distribution network., water; telecommunication, drainage and pollution control facilities, roads, banks, raw materials, storage and marketing outlets, common service facilities and technological backup services for MSEs in the new/ existing industrial estates/areas.
  - a. The location of the Projects should be close to district / block / taluka headquarters or any other development projects with access to the following basic facilities :-
  - i. Proximity to railway stations / state highways to facilitate transport of raw material to, and finished material from the Project;
  - ii. A vailability of water supply and adequate source of power supply. The power position should be reflected in the detailed project report;
  - iii. Telecommunication facilities;
  - iv. The location selected should not create any ecological imbalance by disturbing environment;
  - v. The workers in the project should not be made to travel for more than 8-10 kilometers from their dwelling places;

b. The GoI grant will be restricted to 60% of the cost of project of Rs IO.OO crore. GoI grant will be 80% for projects in NE & Hill States, industrial areas/ estates with more than 50% (a) micro (b) women owned (c) SC/ST units. Details of components for new site development are given at Annex 4. For existing clusters, upgradation proposals will be based on actual requirements.

c. The State/UT Governments will provide suitable land for the Projects. In estimated cost to set up a project under Infrastructure Development projects of Rs.1 0.00 crore (excluding cost of land), Central Government will provide grant-in-aid. The remaining amount may be loan from SJDBIIBanks/Financial Institutions or equity from State/UT Government:

The State/UT Governments will meet the cost in excess of Rs.1 0.00 crore or any escalation in cost.

- d. The project should be completed within two years from the date of final approval, unless extended with the approval of Steering Committee.
- e. Second/ subsequent project in a district will be considered only if the sites developed in the earlier project (s) have been allotted.
- f Funds will be released on reimbursement basis or on matching share basis (Implementing Agency will deposit its share in the dedicated bank account in the name of project and submit a bank certificate). I'' installment limited to Rs. 2 crore only.
- g. State/UT Governments may constitute State Level Comm ittees to coordinate and monitor the progress of implementation of the Projects, with representatives from % DC (MSME), SIDBl, Lead Bank, etc.
- h. Other Conditions:
- i. Construction of sheds/structures shall not be taken up under the scheme. Sheds/structures will be built by the entrepreneurs according to their needs.
- ii. Suitable land endowed with infrastructural facilities like water, electricity, communication and nearness to "mandis" should be selected.
- iii. There should be forward and backward linkages between agriculture and industry. Efforts should be made to use local resources both men and material.
- iv. Any change in the layout plan should be got approved by DC (MSME).

Activity	Implementing Agency					
Diagnostic study	• Offices of the Ministry of MSME					
Soft Interventions	Offices of State Governments					
Setting up of CFC	• National and international institutions					
	engaged in development of the MSE sector.					
	• Any other institution/agency approved by					
	the Ministry of MSME					
Infrastructure	State/UT Governments through an appropriate					
Development projects	state government agency with a good track					
	record in implementing such projects.					

#### **11 Implementation Agencies:**

- 12 Project Approval: The proposals under the scheme will be considered for approval by the Steering Committee of the MSE-CDP. Constitution of the Steering Committee will be: ~
  - I. Secretary (MSME) Chairman
  - II. Additional Secretary & Development Commissioner (MSME)
  - iii. Additional Secretary & Financial Adviser
  - IV. Adviser (YSE), Planning Commission
  - v. Joint Secretary, Ministry of MSME
  - vi. Representative of SIDBI
  - VII. Additional Development Commissioner! Joint Development Commissioner / Director - Incharge of the scheme - Member Secretary
  - VIII.
     Representative(s) of concerned Industry Association(s)
  - ix. Special invitees (financial institutions, programme management service provider, Representative of appraisal agency etc.)
- 12.1 Proposals for DSR, DPR and Soft Interventions will be approved in one stage only.
- 12.2 Hard interventions (CFC) and infrastructure development projects will be approved in two stages: In-principle approval and final approval.
- 12.2.1 In-principle approval: All the proposals should be sent to the office of DC (MSME) through concerned state government. However, institutions of the Ministry of MSME may send proposals for soft interventions/ DSRIDPR directly to the Office of DC (MSME). In case of infrastructure development projects/DPR thereof, State government will submit the proposal to the office of DC (MSME). Office of DC(MSME) may take æsistance of Project Management Service Providers (PMS) for examining of the proposals before considering them for approval. In-principle approval shall be valid for a period of 6 months, and before that it is expected that the project would be ready for final approval. In case, final proposal is not received in 6 months, it will automatically lapse, unless it is specifically extended by the steering committee.
- 12.2.2 Final Approval: The projects which have been accorded in-principle approval, shall be accorded final approval on fulfillment of following conditions:
  - i. Common Facility Center (CFC)
    - a Formation of Spy and Trust building. Role and functions of the SPY should be defined.
    - b Land procured and registered in the name of SPY
    - c Submission of appraised Detailed Project Report (DPR).
    - d Details of the share holding of the SPY
    - e Project Specific account in Schedule A bank
  - ii Infrastructure Development Projects
    - a Submission of appraised DPR with approved layout plan.
    - b Confirmation Of availability of suitable land of the requisite size endowed with infrastructural facilities like water, electricity, communication etc. The land should be in possession in the name of

the Implementing Agency (IA) with Clear Title and complying with Zoning regulations and non-agricultural conversion etc

c Constitution of State Level Committee to coordinate and monitor the progress of implementation of the Projects

- 13 **Programme Management Service Providers (PMS):** Considering the unorganized and micro / small scale nature of enterprises and the need for very extensive project development efforts, especially for industrially backward regions office of DC(MSME) with the approval of the Steering Committee, may appoint competent Programme Management Service Providers (PMS) for facilitating formation of various proposals and their implementation. PMS would act as a link between DC (MSME) and the industry/ state government and would help in efficient and speedy roll out of the Scheme. Office of DC(MSME) will identify, select and prepare a panel of PMSs. The PMS shall report directly to the office of DC (MSME).
  - 13.1 Service charges for the PMS shall be paid from within the approved budget outlay of the scheme.

The PMS will have the following responsibilities:

a Sensitisation and awareness creation about the scheme

b Identification of need for soft and hard interventions and formulation of suitable proposals

c Assist state governments/ industry associations / groups of entrepreneurs / other stakeholder/ agencies in conceptualizing projects and preparing comprehensive proposals / DPRs.

d Assisting the identified entrepreneurs in establishment and structuring the project specific SPY

e Assist office of DC(MSME) in examining the proposals for in-principle and final approval.

f Assist SPY s in selection of agencies / experts for various services and in developing suitable operational framework for CFC

g Assist in periodical monitoring of the progress of the projects and disbursement of funds

h Provide need based advisory services to the office of DC (MSME) and assist in strategy formulation for effective implementation of the scheme

14 Monitoring and Evaluation:

13.2

14.1 The Development Commissioner (MSME) will be the apex body for coordinating and overseeing the progress of the projects.

14.2 In case of projects implemented by the State Governments, their autonomous bodies and SPVs, monitoring of the projects will be the responsibility of the State Governments concerned to ensure satisfactory and time-bound implementation of the activities. Each State Government will also be required to constitute a Project Steering Committee under the chairmanship of Secretary or Director of Industries and consisting of representatives of all stakeholders for this purpose.

14.3 In case of cluster development projects not covered as above, the office of DC(MSME) will directly monitor the progress with the assistance of or through its field level offices.

15 Miscellaneous Provisions

- Monitoring and Management Expenses: At present, interventions are being 15.1 undertaken in more than 400 clusters. Project monitoring and management @ 2 % of the total budget outlay for the sanctioned funds will be uti 1 ized, mainly at the office of DC (MSME) for
  - i. Preparation of panels of PMS/ experts/ expert agencies for preparation of DSRs, DPRs, agencies involved in cluster development, etc.
  - 11. Development of customized software for data management, specialized reports and monitoring & evaluation
  - III. MSE-CDP related communication and stationery expenses
- iv. Travel! exposure visits of the cluster cell officials in the Office of DC (MSME) for monitoring

**MSE-CDP** activities

- v. Organizing of meetings including steering committee ones
- VI Purchase of office automation. equipment like photocopier, maintenance etc. vii. Outsourcing of data management services

  - 15.2 National Level Miscellaneous Activities: Activities (like organizing training/ national workshops, publishing of cluster related material, preparation of study material, deputation of officers from headquarters, specials studies, etc.), setting up of and supporting Resource Centers, which are not part of cluster specific action plans, but are directly connected with the promotion of the scheme and duly approved by the Steering Committee subject to 5% of the total cluster development budget in a particular year, will also be permitted. Training will also be imparted to the Implementing Agencies, SPVs, and other stakeholders as and when required.
  - Cluster development through International Agencies: The interventions criteria/ 15.3 proposal format for cluster develop through International agencies like UNIDO, GTZ, DFID etc do not match with that of the MSE-CDP. However, sometimes it is required to join hand with such agencies with necessary international expertise for development of clusters on national! regional level. Contribution for such programmes may be considered by the Steering Committee in relaxation of the prescribed norms.

Annex 1

## Proposed Budget (Indicative)\* and Means of Finance for Soft Interventions (per cluster spread over a period of 18 months) Rs in Jakh)

S.No.	Description	Max estimated expenditur	Means of Finance.			
			GoI assistance	State Govt. &/or PSU, Institutions	SPV/Priva e Partners	
1.	Trust building (organizing meetings, seminars for cluster actors) 4 meetings	0.80	upt 0 90%			
2.	Building awareness of various schemes of Ministry of MSME, other Ministries and Departments of State & Central Govt, other developmental agencies, Financial institutions etc (2 programmes)	0.80	upto 90%			
3.	Organizing training programmes /seminars/workshops/study tours to other clusters/ demonstration of technology/ equipment, including expert fees, travel, lodging, boarding, etc. (Total upto 6 programmes @ Rs. L00 lakh) ,	6.00	upto 80%			
4.	Capacity building (exposure visits, benchmarking, brochure preparation, web-site launching, initial recruitment cost, etc.)	1.00	upt o 60%			
5.	Services of BDS providers, (max 20 person-days @ Rs 7000/- per day + boarding/lodging charges as per Group A officer's entitlement)	3.00	upto 90%			
6.	Participation in one foreign fair (for entrepreneurs in clusters). One fair per cluster.	5.00	50%			
7.	Miscellaneous developmental costs (translation, publications-lump sum)	1.50	upt 0 80%			
8	In-house institutional Staff: a CDA (if required) -18 month @ Rs. 30000 pm	5.40	upt 0 .50%			
	b Local Organizer/NDA-18 month @ Rs.20000 pm	3.60	upto 50%			
9	Local travel in the cluster of the in- house staff and Telecommunications expenses (Rs 5000 per month)	0.90	100%			
10	Local purchases (computer, telephone, fax-lump sum, year-wise), ifrequired	0.75	100%			
11	Participation of <i>CDE/CDA/</i> cluster official along with entrepreneurs of the cluster. economy! excursion fair + TA	1.25	100%			

- NB Maximum limit for project cost would be Rs 25.00 lakh per cluster. Overall funding pattern will be guided by the details given in para 7b.
- )- After approval of the action plan, changes in the sub-heads up to 25% of the approved amount within the total budget may be allowed with the permission of Director, MSME-DI / DC (MSME).
  - )- \* All the activities mentioned above may not be required in all the clusters. Actual action plan and budget must be prepared on the basis of requirements of the cluster and in close liaison and consent of the cluster beneficiaries/ users body.

Annex 2

#### Format of Detailed Proposal for CFC

The basic details/documentation

- I. Name and location of the cluster
- 11. Nature of activity and products
- III. Number and size (also in terms of instatled capacity) of units
- IV. Scale of investment (also in terms of net fixed and important current assets)
- v. Value of output in the last 5 years (different enterprise segment wise), including export output, if any
- vi. Projected performance of the cluster after proposed intervention (in terms of production, export/domestic sales and direct/indirect employment, etc.)

vii. Diagnostic study/comparative advantage benchmark survey (main findings) vm Information on nature of critical gaps identified (such as poor storage facility, poor testing and quality control facilities-item-wise cost estimates)

- IX. Implementation schedule; structuring of the SPV, such as copy of certificate of incorporation, articles of association and letter of agreement with stakeholders
- x. Revenue generation mechanism for sustainability of assets (service/user charges to be levied, any other-to be specified)
- xi. Project high lights--total cost of project, contribution from cluster enterprises/stakeholders, average contribution by individual enterprises, grant in aid under MSE-CDP, term loans, debt-equity ratio, repayment schedule and estimated debt service coverage ratio (DSCR), annual estimated income, expenditure, gross and net profit at expected/optimal levels of operations, break even (BE)/internal rate of return (IRR) calculations, payback period, etc.

xII. In-principle sanction of loan from a bank, if applicable

- xm. Previous track record of co-operative initiatives pursued by SPY members need to be highlighted with support documentation
- xiv. CFC may be utilised by Spy members as dso others in a cluster. However, evidence should be furnished with regard to SPY member ability to utilise at least 60 per cent of installed capacity.

#### 2. **Elements of DPR**

- 2.1 Plant and machinery
  - (a) List of Plant and Machinery

Sr. No.	Particulars of plant and	No.	Power requirement	F.O.R. Price	Name of proposed	Delivery Schedule
	mac hiner y		(HP/KW)	(Rs)	suppliers	(month- wise)

Note: Add central sales tax, packing and forwarding charges (2%), transit insurance (1%), and freight (2%) to costs or actuals.

(b) Capacity of plant and machinery on single shift basis (c) Production pattern

2.2 Annual requirement of raw materials and consumables at 100% capacity utilization

Sr.		Specifications/	Quantity required	Unit price	Total'
No.	raw material	indigenous/ imported	at full capacity	(Rs.)	value
					(Rs.)

#### 2.3 Utilities and services at full capacity utilization

0P for ind trial

Γ	Sr.	Particulars	of the	KW	No.	of	KW/month	Rs./	Total
	No.	machinery			working			KWH	
					hrs.	per			
I					month				

(b) Power requirement for commercial! domestic purpose (c) Water

(d) Gas/Oill Other utilities

2.4 Site Development and civil construction

	Particulars	Quantity/nos	Rate	Cost
Ι	Cost of land			
11.	Development cost of land			
Itl	Cost of compound wall			
IV	Cost of fabricated gates & grills			
V	Cost of shed			
VI	Cost of laboratory			
Vlt	Other RCC construction			
ix	Water tank! Overhead water tank			
	Total			

#### 2.5 Organizational set up and man power requirement

Sr.	Category/ Designation	No. of persons	Salary	per	Total
No.			month (Rs)		s alary
					(PM)

Note: Add 25% towards fringe benefits and 5% annual mcrement

2.6 Project cost

	Particulars of cost	Amount
(i)	Land & site development	(Rs.)
(ii)	Building	
(iii)	Plant and machinery (cost of plant and machinery, 10% installation, electrification and commissioning)	

	of the Development Commissioner (113ME)
(iv)	Misc. fixed assets (fixture, furniture, fire fighting equipment,
	first aid equipment, back up power supply, etc.)
(v)	Preliminary expenses (diagnostic study, DPR, legal &
	administrative expenses, telephone, stationery, etc.)
(vi)	Pre-operative expenses (establishment, travel, interest on borrowings, committed charges during construction period, start up expenses, etc.)
(vii)	Provision for contingencies (2% building and 5% on plant and machinery)
(viii)	Margin money for working capital
	Total

## 2.7 Means of finance

Sf. No.	Agency	Amount (Rs, lakh)	% of the
1	ODV		project cost
١.	SPY		
2.	GoS		
3.	GoI		
4.	Bank Borrowings		
5.	Others		
	Total		

#### 2.8 Working capital and margin money (actual capacity utilisation year wise)

Sr.	Particulars	No. of	Mar	as per o	capacity utilis	ation
0.		month	gin	1 sı year	2 <sup>na</sup> Year	3 <sup>rCl</sup>
1.	Raw material and consumables					vear
2.	Utilities	I.				
3 4.	Working expenses (salary of manpower) Works in process (cost of raw material, utility and salary on	1				
5.	actuals) Stock of finished goods (cost of raw material, utility, salary, factory overheads on actuals)					
6.	Bills receivables (Sales value)					
	Total					

2.9 Cost of production (projection for 10 years of operation in tabular form)

- (i) Raw materials and consumables
- (ii) Utilities
- (iii) Wages and salary
- (iv) Repairs and maintenance
- (v) Insurance

- (vi) Administrative and factory overheads
- (v i i) Selling expenses

2.10 Estimation of profitability (projections for 10 years of operation in tabular form)

- (i) Installed capacity
- (ii) Number of working days (single shift basis)
- (iii) Capacity utilization
- (iv) Production (in single unit)
- (v) Sales realisation
- (vi) Cost of production
- (vii) Gross profit [(v)-(vi)]
- (viii) Financial expenses
- (a) Interest on bank borrowing
- (ix) Depreciation on written down value method (as per separate schedule to be attached for different categories affixed assets)
- (x) Preparatory expenses not written off
- (xi) Operating profit [(vii) {(viii) + (ix) + (x)}]
- (xii) Tax vide separate schedule
- (xiii) Profit after tax [(xi) (xii)]
- (xiv) Available surplus [(xiii) + (ix)]
- 2.11 Cash flow statement (projections for 10 years in tabular form)
  - (A) Sources of fund:
    - (a) Gross profit less depreciation
    - (b) Term loan
    - (c) Subsidy/Grant
    - (d) Promoter's contribution
    - (e) Increase in bank borrowings
    - (f) Depreciation
  - (B) Disposal of funds:
    - (a) Preliminary & pre-operative expenses
    - (b) Capital expenditure
    - (c) Increase in working capital
    - (d) Interest on term loan
    - (e) Interest on bank borrowings
    - (f) Decrease in term loan
    - (g) Taxes
  - (C) Opening balance of cash in hand or at bank [sum total of  $\{(A)-(B)\}$ ]
  - (D) Net surplus/Deficit
  - (E) Closing balance of cash in hand or at bank

#### 2.12 Debt Service coverage ratio (Projections for 10 years) DSCR = Net

- Pr *ojit* + Interest(TL) + Depreciation installment(TL) + Interest (TL)
- 2.13 Balance sheet & PIL account (projection for 10 years)

2.14 Break Even Point = <u>Fixed Cost</u>

Contributioni Sales - Variable Cost)

3 **Commercial Viability:** Following financial appraisal tools will be employed for assessing commercial viability of the project:

- (i) **Return on Capital Employed (ROCE):** The total return generated by the project over its entire projected life will be averaged to find out the average yearly return. The simple acceptance rule for the investment is that the return (incorporating benefit of grant-in-aid assistance) is sufficiently larger than the interest on capital employed. Return in excess of 25% is desirable.
- (ii) **Debt Service Coverage Ratio**: Acceptance rule will be cumulative DSCR of 3:1 during repayment period.
- (iii) Break-Even (BE) Analysis: Break-even point should be below 60 per cent of the installed capacity.
- (iv) Sensitivity Analysis: Sensitivity analysis will be pursued for all the major financial parameters/indicators in terms of a 5-10 per cent drop in user charges or fall in capacity utilisation by 10-20 per cent.
- (v) **Net Present Value (NPV):** Net Present Value of the project needs to be positive and the Internal Rate of return (IRR) should be above 10 per cent. The rate of discount to be adopted for estimation of NPY will be 10 per cent. The project life may be considered to be a maximum of 10 years. The life of the project to be considered for this purpose needs to be supported by recommendation of a technical expert/institution.

Annex 3

#### <u>Format for Tripartite Agreement among Special Purpose Vehicle (SPV), State</u> <u>Government and Government ofIndia under MSE-CDP</u>

**WHEREAS** the Gol has introduced a scheme named as 'Micro and Small EnterprisesCluster Development Programme (MSE-CDP)" with the objective of capacity building of micro and small enterprises (including small scale service and business entities) and their collectives in the country;

AND WHEREAS the Spy has submitted a project for approval of the Go1 under the MSECDP;

AND WHEREAS for binding the Parties to their respective obligations and to ensure long term use of the CFC by the enterprises in the Cluster, the Parties are desirous to enter into an agreement;

#### NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:-

- 1. The SPY shall set up the CFC at. ..... on a piece of land to be provided by it free of all encumbrances and charges.
- 2. The SPY shall contribute to the cost of establishment of the CFe from its resources to the extent and in the form as laid down in the Sanction Letter.
- 3. The Gol and the GaS shall, on satisfactory proof of the contribution by the SPY, make their respective contributions towards the cost of establishment of the CFC, at such time, in such manner and to such extent as laid down in the Sanction Letter.
- 4. The establishment of the CFC, including civil works, if any, shall be completed by the SPY within one year of the receipt of the Sanction Letter, or such extended time as the Gel may, on its satisfaction as to the reasons of delay, grant.
- 5. The SPY shall be exclusively responsible for the day-to-day running of the CFC. The aim of running the CFC shall be to provide common services to the enterprises

in the Cluster at affordable cost as well as to generate enough income to meet all its running expenditure, depreciation and provision for replacement/expansion of capital assets. However, any shortfall or excess of income over expenses shall be kept or borne by the SPY only.

- 6. The disbursement of funds by the Gal will be made only after the upfront contribution to be made by the SPY, the State Government or the beneficiaries.
- 7. Further, the SPY/implementing agency will ensure that necessary infrastructure like provisioning of land and building including water and power supply for CFC is completed before they approach Gol for release of its share.
- 8. Pending utilization of Gal grant, the funds will be parked in a separate dedicated account created for this purpose. Interest accrued, if any, on unutilized fund shall be adjusted against future disbursement under the scheme.
- 9. Gal will reserve the right to carry out physical verification of the assets acquired with the funds or initiate any other enquiry as it may deem fit to satisfy the competent authority with regard to the proper util ization of the funds released.
- 10. The SPY shall furnish utilization certificates for amounts released as grant-in-aid duly verified by the statutory auditors.
- 11. The GaS will act as a facilitator to supervise and evaluate the progress of the project separately. The GaS will also inform the Gal about the status of the establishment or running of CFC and shall also report to the Gal for any discrepancies in its management or otherwise.
- 12. All plant, machinery, fixtures or equipment procured for the purpose of the *CFC* out of or with the support of the Gal or GaS grant shall be the exclusive property of the GaS, though in the custody and use of the Spy.
- 13. The SPY shall, at its own cost, insure and keep insured all the plant, machinery, fixtures and equipment of the CFC for a minimum period of 10 years. In case of loss of or damage to such plant, machinery, fixtures and equipment, etc., the insurance monies shall be payable to the GaS.
- 14. The SPY shall observe all the conditions and stipulations of the Sanction Letter.
- 15. The management of the SPY and the operation of the *CFC* shall be in accordance with the Gal Guidelines dated ....., which shall be deemed to be a part of this Agreement.
- 16. The Spy shall keep all monies not immediately required in interest bearing deposits with any Scheduled Bank in India.
- 17. In the event of any liquidation or bankruptcy proceedings or any threatened distress action against the Spy or any of its assets all plant, machinery, fixtures and equipment procured for the purpose of the CFC out of or with the support of the Gal or GaS grant shall be outside such proceedings and the Gal may assume the control and management of the SPY and appoint any of its officer or officer of the GaS or any semi-government or non-government body to run the CFC.
- 18. The SPY represents and warrants:
  - A. That it has been duly constituted under the law as applicable and has full authority to enter into th is Agreement.
  - B. That this agreement is binding upon it in all its provisions.
  - C. That it shall work on mutual co-operation basis on sound managerial and business principles and no managerial changes shall be made which may adversely affect the smooth functioning of the CFC.
  - D. That it shall keep all the plant, machinery, fixtures and equipment in good working order and shall undertake all preventive and remedial maintenance and upkeep and maintain insurance.

- E. That the plant, machinery, fixtures and equipment procured out of or with support of the Gal and GaS grant, is the property of GaS and the SPY shall not sell, hypothecate, mortgage, charge or create any encumbrances against the said plant, machinery, fixtures and equipment or any part of it in favour of any person, for any reason or transaction.
- F. That the SPY shall follow the directions of the Gel and GaS, as may be issued from time to time for better management of the Spy or the better running of the CFC.
- G. That the Spy acknowledges that the MSE-CDP provides for only one time grant towards capital cost of establishing the CFC and no subsidy/grant/assistance is envisaged for the recurring expenses or for replacement, renovation or expansion of the capital assets.
- H. In the event it is found that the SPY has not utilized the amount of grant, or any part of it, for the setting up of the CFC or has subsequently sold or otherwise disposed of any of the assets of the CFC acquired out of the grant, the Gal, without prejudice to any other rights, shall be entitled to recover the amount of loss as arears of land revenue. from the SPY and / or persons connected with its management jointly and severally.
- 19. In case of any disputes or differences arisi ng from in relation to or in connection with this Agreement and not otherwise provided for in the succeeding clause, shall be settled by arbitration through reference to a sale arbitrator. nominated by the Secretary, Department of Legal Affairs, Government of India, ew Delhi (the Law Secretary). The provisions of the Arbitration and Conciliation Act, 1996 shall apply to the arbitration proceedings. Courts in Delhi shall have exclusive jurisdiction in all the matters.
- 20. In case of violation of the stipulated conditions or non observance of the Sanction Letter or the Gal Guidelines by the SPY which is not cured within 15 days of issue of notice by the Gal, the GoT in consultation with the GaS, may, for such time as it may think proper, assume the management of the SPY or delegate the same to the GaS, or a semi-government or non-government body, to assure proper functioning of the CFC. The decision of Gal in this regard will be final. In such event the SPY shall have no claims for any investment made in the CFC or its management.
- 21. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of the remaining provisions, which shall remain in full force.
- 22 Failure or delay on the part of Gol in insisting upon strict performance by the SPY or in taking action against the SPY, or grant of time or any other indulgence by the Gal, shall not be deemed to be waiver of any breach nor waiver on any occasion of breach shall be deemed to be a waiver for other occasions or other breaches.
- 23. No amendment to this agreement shall be valid unless expressed in writing and duly signed by all the Parties.
- 24. This agreement does not constitute any partners hip of the Gol or the GaS with the SPY and the Gal and the GaS shall not be responsible for any act, omission, negligence, etc. of the SPV or its employees, agents or contractors or any injury suffered or claim made by any person in respect of the working of the CFC.

**SECRET** 

#### No. 1 (I7)/SICDP/ClustersrrM-2006 Government ofTndia Ministry of Micro, Small & Medium Enterprise (MSME) Office of the Development Commissioner (MSME)

Annex 4

## Details of Project Cost for Infrastructure Development for New Sites

S. No.		Items	Rs.1	akh	
1.	Lan	d Development and other overhead Infrastructure			
	I.	Cost of land filling/leveling including boundary ball / fencing	100		
	ii.	Cost of laying roads	200		
	iii.	Road side greenery & social forestry	10		
	IV.	Water supply including overhead tanks, and pump houses	110		
	ν.	Water harvesting	10		
	vi. Drainage				
	vii.	Power (Sub-Station and distribution net-work work including Street light etc), Generation of non-conventional energy	250		
	Vll1.	Others (Sanitary Conveniences etc.)	10		
		Sub Total		750	
2.	Adm	ninistrative and Other Services Complex			
	i.	Administrative Office Building	20		
	II.	Telecommunication /Cyber Centre/ Documentation Centre	20		
	П1.	Conference Hall/ Exhibition centre)	30		
	IV.	Bank! Post Office	20		
	V.	Raw material storage facility, Marketing outlets	40		
	VI.	First Aid Centre, Creche, Canteen facilities	20		
		Sub Total		150	
3.	Efflu	uent Treatment Facilities		80	
4.	Cont	ingencies & Pre-operative expenses		20	
		GRAND TOTAL		1000	