(A) Assistance to Pharmaceutical Industry for Common Facilities

(1) The Scheme

(i) A Central Sector Scheme for Assistance to Pharmaceutical Industry for Common Facilities.

(ii) The Scheme would be implemented in a Public Private Partnership (PPP) mode 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.

(iii) The various aspects and outcomes of the Scheme will be reviewed after two years from the date of its initiation.

(2) Objective

(i) Strengthening the existing infrastructure facilities in order to make Indian Pharma Industry a global leader in Pharma Sector.

(ii) Easy access to standard testing facilities and value addition in the domestic Pharma Industry especially to SMEs through creation of common world class facilities for increased competitiveness.

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

(iv) Exploit the benefits arising due to optimization of resources and economies of scale.

(3) Scope and Coverage

Assistance under the Scheme will be admissible for creation of Common Facilities by Government as well as Private Entrepreneurs in pharma sector.

(4) Common Facilities

Common Facilities under the Sub-Scheme 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 Centres
(ii) Training Centres
(iii) R&D Centres
(iv) Effluent Treatment Plants
(v) Common Logistics Centres

The above list of common facilities is illustrative and each cluster could have its own specific requirement 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.

(5) Salient Features of the Scheme

(i) The land and building for CFC shall be provided by SPV concerned as per cost indicated in the detailed project report. In case the SPV provides an existing land and building, the cost of the same will be decided on the basis of valuation report prepared by an approved agency of Central/State Government Departments/Financial Institutions (FIs)/Public Sector Banks and the cost of land and building may be taken towards contribution for the project. Though the land and building is included in the total project cost, however, the Grant-in-Aid from GoI will not be utilized for these components.

(ii) Escalation in the cost of project over and above the sanctioned amount, due to any reason will be borne by the SPV. The Central Government shall not accept any financial liability arising out of operation of any CFC.

(iii) The Grant-in-Aid shall not be available to any individual production units, if any, owned by a member of the SPV.

(iv) The CFC may be utilized by the SPV members and also by other pharma units on 'user charges' basis to be decided by the SPV.

(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 lesser than prevailing market prices, as decided by the Governing Council of the SPV. The SPV members would be given reasonable preference in user charges.

(vi) An MoU shall be entered into among the GOI, the State Government concerned and the SPV for CFC projects.

(6) Implementation Process

(i) Special Purpose Vehicle (SPV)

It is necessary to form an SPV prior to setting up of and running the proposed CFC. The SPV should be a clear legal entity registered under the Company Act or Registration of Societies Act. The SPV should have a provision for enrolling new members to enable prospective entrepreneurs in the cluster to utilize the facility which is being provided.

There shall be a minimum of 3 pharma units (including Bulk Drug and Medical Device Units) as members of Special Purpose Vehicle (SPV). There is no ceiling on the maximum number of members in the SPV.

However, where only State Government or an agency of the State Government is applicant under the Scheme without private participation, the SPV formation may not be insisted upon, instead they should just create an Escrow/TRA account so that funds are utilized only for the project purpose.

(ii) <u>Detailed Project Report (DPR)</u>

A Detailed Project Report (DPR) will be prepared by the SPV at its own cost. 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., impediments and bottlenecks need to be identified; and action plan for enhancing competitiveness of the units of the cluster and positioning the cluster on a self-sustaining trajectory of growth be drawn. 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.

(7) <u>Other Requirements for availing of the benefits under the Scheme</u>

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

(i) It should preferably 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) SPVs may dovetail funds from other sources as well for the project, provided there is no duplication of funding for the same component/ intervention. Resources raised through such dovetailing however, will be in addition to the 30% contribution of the SPV.

(8) <u>Financial Assistance</u>

(i) Maximum limit for the grant in aid under this category would be Rs 20.00 crore per cluster or ***70% of the cost of project*** whichever is less. The cost of project includes cost of land, building, 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. Grant-in-Aid from GoI will not be utilized towards land and building components of the project.

(ii) Assistance for Administrative and other management support of SPV during the project implementation period shall not exceed 5 % of the Grant-in-aid.

(iii) Proportionate 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.

(iv) User charges for services of CFC, shall be on a differential rate basis, lower fee for units dedicated to manufacture of the products in the premises of SPV. In any case, the user charges will have to be graded in such a manner that average user charges are close to prevailing market prices for such services.

(v) Funds will be released in instalments depending upon the implementation plan, requirements of funds and as approved by the Scheme Steering Committee (SSC).

(9) Time Frame for Project Implementation

The implementation of the approved project will be completed in 2 years from the date of approval of the projects. However, limited period extension may be considered by Scheme Steering Committee for circumstances beyond the control of SPV.

(10) Eligibility Criteria for Special Purpose Vehicle (SPV)

(i) The project will be implemented through a Special Purpose Vehicle (SPV) which will have a minimum of 3pharma units (including Bulk Drug and Medical Device Units) as its shareholders.

(ii) The SPV may have the representatives from cluster members, financial institutions, State and Central Government and R&D organizations. The SPV shall have full operational autonomy to develop, operate and maintain the infrastructure.

(iii) Pharma enterprises shall hold at least 51% equity of the SPV.

(iv) The combined net worth of members of SPV shall be equivalent to total grant-amount applied for and each SPV member must have a net worth of at least 1.5 times of their proposed equity contribution.

(v) The SPV members 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.

(11) Role of Special Purpose Vehicle

SPV 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.

(12) Project Management Consultant (PMC)

(i) The SSC 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 SSC 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 SSC.

(ii) The PMC will be selected through an open transparent and competitive bid process.

(iii) The PMC will report directly to the SSC and shall have the following responsibilities:-

(a) Sensitisation of the industry/ potential beneficiaries on the scheme and its benefits and also guiding them to form SPV, in drafting its Memorandum and Article of Association.

(b) To assist DoP in drafting and issuing Expression of Interest (EOI) for inviting projects under the Scheme.

(c) Formulating evaluation criteria and to assist DoP in selection of Projects from the proposals received in response to EOI.

(d) Appraisal of the DPRs indicating financial viability, commercial sustainability and socio-economic impact for according final approval to the projects.

(e) To assist the SPV in achieving financial closure and obtaining necessary clearances from various authorities for the project.

(f) Assist the DoP in periodical monitoring of the progress of the projects, and disbursement of funds to the SPVs and their utilization.

(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.;

(i) Provide other need based advisory services to the SPV in effective implementation of the scheme;

(13) 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) Undertaking equity stake in the SPV, where there is a possibility of development of projects together with the SPV.

(c) Providing flexible and conducive environment and consider special facilities like exemption of stamp duty etc. for the SPV/ units.

(d) Dovetailing assistance available under related schemes for overall effectiveness and viability of the projects.

(e) Providing necessary project related clearances expeditiously.

(14) Project Approval

A. **Scheme Steering Committee (SSC)**

(i) The Department of Pharmaceuticals (DoP) will provide 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 Scheme.

(ii) The composition of the Scheme Steering Committee will be as follows:-

- (i) Secretary, DoP - Chairperson
- (ii) Financial Adviser, DoP-Member
- (iii) Joint Secretary(Policy), DoP- Convenor

(iii) The SSC may co-opt representatives of any Pharma Industry Associations, Financial Institutions/Programme Management Consultant, R&D Institutions and Other Government/ Private sector expert organizations as members or special invitees as may be necessary from time to time.

(iv) 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.

(B) In-principle Approval:

In-principle approval for a project will be accorded by 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. 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.

(C) 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 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 Current Account, 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.

(15) <u>Guidelines for Release of Funds</u>

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) in the following manner:-

Instalment	Percentage of Funds	Remarks/ Pre-requisite
1	30	• mobilization advance against an Indemnity Bond, on final approval of the project by SSC
2	30	• against the production of Bills • the utilisation of at least 60% of the 1st instalment and after the proportionate expenditure has been incurred by the SPV
3	30	• against the production of Bills • 100% utilisation of 1st instalment and at least 60% utilization of 2nd instalments and after the proportionate expenditure has been incurred by the SPV
4	10	• SPV has mobilized and spent its entire share in proportion to grant

The SPV shall submit the Utilisation Certificate (UC) in prescribed form GFR-12A for the amounts utilized in accordance with GFR-2017.

Accounts of SPV shall be subject to audit by the Comptroller & Auditor General of India.

(16) 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.

(iv) A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by GOI should be maintained as per GFR.

(v) 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.

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