

GUIDELINES FOR IMPLEMENTATION OF THE FIVE SUB-SCHEMES UNDER THE SCHEME FOR DEVELOPMENT OF PHARMACEUTICALS INDUSTRY

(A) Assistance to Bulk Drug Industry for Common Facility Centre

(1) Objective

- (i) Increasing the competitiveness, easy access to standard testing and infrastructure facilities and value addition in the domestic Bulk Drug Industry through creation of common world class facilities.
- (ii) Strengthening the existing infrastructure facilities in order to make Indian Bulk Drug Industry a global leader in Bulk Drugs' Exports.
- (iii) Reducing the cost of production by 20-25% in the Bulk Drug Park leading to better availability and affordability of Bulk Drugs in domestic market.
- (iv) Exploiting the benefits arising due to optimization of resources and economies of scale.

(2) The Scheme

- (i) The Scheme termed as Development of Common Facility Centre for Bulk Drug (DCFC-BD) is proposed as a Central Sector Scheme.
- (ii) The total size of the scheme is proposed as Rs. 200 Crores for DCFC-BD for 2018-2020.
- (iii) The Scheme would be implemented through a one-time grant-in-aid to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose.
- (iv) The purpose of the grant is to render the financial assistance for establishment of common facilities in any upcoming Bulk Drug Park promoted by State Governments/State Corporations.
- (v) The various aspects and outcomes of the Scheme will be reviewed by the SSC in DoP, after two years from the date of its initiation.

(3) Scope and Coverage

Assistance under the Scheme will be admissible for creation of common facilities in Bulk Drug Park.

(4) Common Facilities

A State Implementing Agency (SIA) should be set up to take a decision about the Common Infrastructure facilities needed to be created for being eligible to be considered as a Common Facility Centre (CFC) for a Bulk Drug Park. Such assessment will depend upon the nature of manufacturing projects likely to be set up in any selected Bulk Drug Park. Common Facilities under the sub-scheme will consist of creation of tangible "assets" as Common Facility Centres (CFCs). Some of the indicative activities under the Common facilities are:-

- (i) Effluent Treatment Plants
- (ii) Captive Power Plants
- (iii) Steam and Cooling systems
- (iv) Incubation facilities
- (v) Common logistic facilities
- (vi) Advance common testing Centre
- (vii) Regulatory awareness facilitation Centre
- (viii) Emergency Response Centre

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

- (i) The land and building for CFC shall be provided by SIA concerned as per cost indicated.
- (ii) The CFC should be operationalized within two years from the date of final approval, unless extended with the approval of Scheme Steering Committee (SSC).
- (iii) Escalation in the cost of project over and above the sanctioned amount, due to any reason, will be borne by the SIA. The Central Government shall not accept any financial liability arising out of operation of any CFC.
- (iv) 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 to be decided by the concerned SIA.
- (v) A Tripartite Agreement shall be entered into among the GOI, the State Government concerned and the SIA for CFC projects.

(5) Eligibility

(i) State Implementing Agency

It is necessary to form a SIA prior to setting up of and running the proposed CFC. An SIA is a clear legal entity set up by the State Government for implementing the Bulk Drug Park Project and responsible for the day to day management of the Bulk Drug Park.

(ii) Detailed Project Reports (DPR)

A Detailed Project Report (DPR) has to be prepared by the SIA and submitted to the Department of Pharmaceuticals (DoP) as the first and foremost activity for availing assistance under this sub-scheme. The DPR should have details of all the business processes of the Bulk Drug Parks 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 to be set up in the Bulk Drug Parks.

(6) Financial Assistance

- (i) Maximum limit for the grant in aid under this category would be Rs. 100 Crores per Bulk Drug Park CFC or 70% of the project cost of CFC whichever is less. 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) Assistance for Administrative and other management support of **SIA** including the salary of CEO for the project implementation period shall not exceed 5 % of the Grant-in-aid.
- (iii) Assistance for engaging engineers and other experts for execution of civil works shall not exceed 5% of the Grant in Aid.
- (iv) 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 GoI 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 GoI assistance.

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

(7) Other Requirements of Common facility Centres

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

- (i) It shall be the responsibility of the SIA to bring in land as its contribution;
- (ii) The CFC set up with the financial assistance under this scheme should be economically viable so as to generate adequate revenue for its sustenance.

(8) Time Frame for CFC Project Implementation

The time frame for implementation of a SSC approved CFC project would be 2 years from the date of its approval.

(9) State Implementing Agency

(i) Although SIA/Project Implementing Agency would fulfil 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 assigned to the SIA would be as follows:

- (a) Prepare the Detailed Project Report covering the technical, financial, institutional **operational** aspects of the CFC 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) To furnish regular progress report directly to Department of Pharmaceuticals (DoP) and SIA shall have the following responsibilities:-
 - (i) Appraisal of the DPRs indicating financial viability, commercial sustainability and socio-economic impact for according final approval to the projects.
 - (ii) Assist DoP in formulating a suitable strategy for implementation of the scheme.
 - (iii) Assist the DoP in periodical monitoring the progress of the projects, and disbursement of funds and their utilisation.

(10) Role of State Governments

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

- (a) Promoting the Bulk Drug Park aggressively at National & International level.
- (b) Undertaking equity stake in the SIA.
- (c) Providing the necessary assistance for external/ access infrastructure as land, access road, Power and Water supply etc.
- (d) Providing flexible and conducive environment and consider special facilities like exemption of stamp duty etc. for the SIA/ individual Bulk Drug units to be set up in the Park.
- (e) Providing necessary project related clearances expeditiously

(11) Implementation Framework

Scheme Steering Committee (SSC)

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 DCFC-BD.

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

- i. Secretary, DoP - Chairperson
- ii. Financial Adviser, DoP-Member
- iii. Joint Secretary, M/o EF&CC-Member
- iv. Joint Secretary, D/o IPP-Member
- v. Joint Secretary, M/o H&FW-Member
- vi. DCGI, CDSCO- Member
- vii Representative of State Implementing Agency (SIA)- Member
- vii Joint Secretary(Policy), DoP-Convenor

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

(12) Project Approval for setting up of CFC

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 SIA/State Government 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 SIA;
- ii. Procurement of requisite land by the SIA;
- iii. Preparation of DPR by SIA and its appraisal by SSC
- iv. Opening of separate bank account for the purpose by the SIA with any scheduled commercial bank. The funds to be released by Department of Pharmaceuticals, Government of India under this sub-scheme shall be transferred to the said account of SIA.
- v. 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 SIA and approved by the Scheme Steering Committee (SSC) in the following manner:-

Instalment	Percentage of Funds	Remarks/ Pre-requisite
1	30	<ul style="list-style-type: none">• mobilization advance against an Indemnity Bond, on final approval of the project by SSC
2	30	<ul style="list-style-type: none">• 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 SIA
3	30	<ul style="list-style-type: none">• against the production of Bills• 100% utilisation of 1st instalment and at least 60% utilization of 2ndinstalments and after the proportionate expenditure has been incurred by the SIA
4	10	<ul style="list-style-type: none">• SIA has mobilized and spent its entire share in proportion to grant

The SIAs shall submit the Utilisation Certificate (UC) for the amounts utilized as per the format in accordance with GFR 12A;

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

(14) Maintenance /Ownership of Assets

- (i) SIA shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/ users;
- (ii) The Assets acquired by the SIA out of government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.
- (iii) 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.
- (iv) If for any reason SIA 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 SIA with the Government shall incorporate this condition.

(15) Miscellaneous Provisions

15.1 Monitoring and Management Expenses: Project monitoring and management expenditure will be limited to maximum 1% of the total budget outlay of the sanctioned funds will be utilised. The main activities for which these funds will be utilized include, mainly in DoP:-

- (i) Preparation of panels of Pharma Regulatory Affair Experts/Agencies for preparation of Detailed Project Report for assistance for eligible activities in the Bulk Drug Park.
- (ii) Expenditure involved in site visits of the Bulk Drug Park for monitoring of progress and evaluation of the scheme.

- (iii) Development of customized software for data management, specialized reports, monitoring and evaluation.
- (iv) Bulk Drug Park related publicity material for awareness generation.
- (v) Organization of meeting of various Committees including the Scheme Steering Committee (SSC).
- (vi) Purchase of office automation equipment like photocopier, maintenance etc.
- (vii) Outsourcing of Data management services.

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(B) Assistance to Medical Device Industry for Common Facility Centre

(1) Objective

- (i) Increase the competitiveness, easy access to standard testing facilities and value addition in the domestic Medical Device industry through creation of common world class facilities.
- (ii) Strengthening the existing infrastructure facilities in order to make Indian Medical Device industry a global leader in pharma or devices exports.
- (iii) Reducing the cost of production significantly in the Medical Device Park leading to better availability and affordability of Medical Devices in domestic market.
- (iv) Exploit the benefits arising due to optimization of resources and economics of scale.

(2) The Scheme

- (i) The Scheme termed as Development of Common Facility Centre for Medical Device (DCFC-MD) is proposed as a Central Sector Scheme.
- (ii) The total size of the scheme is proposed as Rs. 100 Crores for DCFC-MD for 2018-2020.
- (iii) The Scheme would be implemented through a one-time grant-in-aid to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose.
- (iv) The purpose of the grant is to render the financial assistance for establishment of common facilities in any upcoming Medical Device Parks promoted by State Governments/State Corporations.
- (v) The various aspects and outcomes of the Scheme will be reviewed by the SSC in DoP after two years from the date of its initiation.

(3) Scope and Coverage

Assistance under the Scheme will be admissible for creation of common facilities in Medical Device Park:

(4) Common Facilities

A State Implementing Agency (SIA) should be set up to take a decision about the Common Infrastructure facilities needed to be created for being eligible to be considered as a Common Facility Centre(CFC) for a Medical Devices Park. Such assessment will depend upon the nature of manufacturing projects likely to be set up in any selected Medical Devices Park. Common Facilities under the sub-scheme will consist of creation of tangible "assets" as Common Facility Centres (CFCs). Some of the indicative activities under the Common facilities are:-

- (i) Component Testing Centre
- (ii) Electro-magnetic interference laboratory
- (iii) Biomaterial / Biocompatibility testing centre
- (iv) Medical grade low vacuum moulding
- (v) Cabinet moulding
- (vi) injection moulding centers
- (vii) 2D designing and printing for medical grade products
- (viii) Sterilization and Toxicity testing centre
- (ix) Radiation testing centre, etc.

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

- (i) The land and building for CFC shall be provided by SIA concerned as per cost indicated.
- (ii) The CFC should be operationalized within two years from the date of final approval, unless extended with the approval of Scheme Steering Committee (SSC).
- (iii) Escalation in the cost of project over and above the sanctioned amount, due to any reason, will be borne by the SIA. The Central Government shall not accept any financial liability arising out of operation of any CFC.
- (iv) 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 to be decided by the concerned SIA.
- (v) A Tripartite Agreement shall be entered into among the GOI, the State Government concerned and the SIA for CFC projects.

(5) Eligibility

(i) State Implementing Agency

It is necessary to form a SIA prior to setting up of and running the proposed CFC. An SIA is a clear legal entity set up by the State Government for implementing the Medical Device Park Project and responsible for the day to day management of the Medical Device Park.

(ii) Detailed Project Reports (DPR)

A Detailed Project Report (DPR) has to be prepared by the SIA and submitted to the Department of Pharmaceuticals (DoP) as the first and foremost activity for availing assistance under this sub-scheme. The DPR should have details of all the business processes of the Medical Device Parks 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 to be set up in the Medical Device Parks.

(6) Financial Assistance

- (i) Maximum limit for the grant in aid under this category would be Rs. 25 Crores per Medical Device Park CFC or 70% of the project cost of CFC whichever is less. 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) Assistance for Administrative and other management support of SIA including the salary of CEO for the project implementation period shall not exceed 5 % of the Grant-in-aid.
- (iii) Assistance for engaging engineers and other experts for execution of civil works shall not exceed 5 % of the Grant in Aid.
- (iv) 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 GoI 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 GoI assistance.

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

(7) Other Requirements of Common facility Centres

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

- (i) It shall be the responsibility of the SIA to bring in land as its contribution;
- (ii) The CFC set up with the financial assistance under this scheme should be economically viable so as to generate adequate revenue for its sustenance.

(8) Time Frame for CFC Project Implementation

The time frame for implementation of a SSC approved CFC project would be 2 years from the date of its approval.

(9) State Implementing Agency

(i) Although SIA/Project Implementing Agency would fulfil 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 assigned to the SIA would be as follows:

- (a) Prepare the Detailed Project Report covering the technical, financial, institutional operational aspects of the CFC 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) To furnish regular progress report directly to Department of Pharmaceuticals (DoP) and SIA shall have the following responsibilities:-
 - (i) Appraisal of the DPRs indicating financial viability, commercial sustainability and socio-economic impact for according final approval to the projects.
 - (ii) Assist DoP in formulating a suitable strategy for implementation of the scheme.
 - (iii) Assist the DoP in periodical monitoring the progress of the projects, and disbursement of funds and their utilisation.

(10) Role of State Governments

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

- (a) Promoting the Medical Device Park aggressively at National & International level.
- (b) Undertaking equity stake in the SIA.
- (c) Providing the necessary assistance for external/ access infrastructure as land, access road, Power and Water supply etc.
- (d) Providing flexible and conducive environment and consider special facilities like exemption of stamp duty etc. for the SIA/ individual Medical Device units to be set up in the Park.
- (e) Providing necessary project related clearances expeditiously

(11) Implementation Framework

Scheme Steering Committee (SSC)

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 DCFC-MD.

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

- i. Secretary, DoP - Chairperson
- ii. Financial Adviser, DoP- Member
- iii. Joint Secretary, D/o IPP-Member
- iv. Joint Secretary, M/o H&FW- Member
- v. DCGI, CDSCO- Member
- vi. Representative of State Implementing Agency (SIA)- Member
- vii. Joint Secretary(Policy), DoP-Convenor

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

(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 SIA/State Government 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 SIA;
- (ii) Procurement of requisite land by the SIA;
- (iii) Preparation of DPR by SIA and its appraisal by SSC
- (iv) Opening of separate bank account for the purpose by the SIA with any scheduled commercial bank. The funds to be released by Department of Pharmaceuticals, Government of India under this sub-scheme shall be transferred to the said account of SIA.
- (v) 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 SIA and approved by the Scheme Steering Committee (SSC) in the following manner:-

Instalment	Percentage of Funds	Remarks/ Pre-requisite
1	30	<ul style="list-style-type: none">• mobilization advance against an Indemnity Bond, on final approval of the project by SSC
2	30	<ul style="list-style-type: none">• 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 SIA
3	30	<ul style="list-style-type: none">• against the production of Bills• 100% utilisation of 1st instalment and at least 60% utilization of 2ndinstalments and after the proportionate expenditure has been incurred by the SIA
4	10	<ul style="list-style-type: none">• SIA has mobilized and spent its entire share in proportion to grant

The SIAs shall submit the Utilisation Certificate (UC) for the amounts utilized as per the format in accordance with GFR 12A;

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

(14) Maintenance /Ownership of Assets

- (i) SIA shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/ users;
- (ii) The Assets acquired by the SIA out of government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.
- (iii) 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.
- (iv) If for any reason SIA 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 SIA with the Government shall incorporate this condition.

(15) Miscellaneous Provisions

15.1 Monitoring and Management Expenses: Project monitoring and management expenditure will be limited to maximum 1% of the total budget outlay of the sanctioned funds will be utilised. The main activities for which these funds will be utilized include, mainly in DoP:-

- (i) Preparation of panels of Pharma Regulatory Affair Experts/Agencies for preparation of Detailed Project Report for assistance for eligible activities in the Medical Device Park.
- (ii) Expenditure involved in site visits of the Medical Device Park for monitoring of progress and evaluation of the scheme.

- (iii) Development of customized software for data management, specialized reports, monitoring and evaluation.
- (iv) Medical Device Park related publicity material for awareness generation.
- (v) Organization of meeting of various Committees including the Scheme Steering Committee(SSC).
- (vi) Purchase of office automation equipment like photocopier, maintenance etc.
- (vii) Outsourcing of Data management services.

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(C) **Assistance for Cluster Development**

(1) **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.

(2) **The Scheme**

- (i) The Scheme termed as Cluster Development Programme for Pharma Sector (CDP-PS) as a Central Sector Scheme.
- (ii) The total size of the scheme is proposed as Rs. 20 Crores for CDP-PS for 2018-2020.
- (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.
- (iv) The various aspects and outcomes of the Scheme will be reviewed after two years from the date of its initiation.

(3) **Scope and Coverage**

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

(4) **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 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/ Financial Institutions (Fls) /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 operationalized 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. 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 not be higher than the 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 for Common Facility Centers

(i) Special Purpose Vehicle (SPV)

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 with in the proposed cluster. The SPV should have a provision for enrolling new members to enable prospective entrepreneurs in the cluster to utilize the facility is being provided. In addition to the contribution members of the SPV, the organizers should obtain return commitments from ‘users’ of the proposed facilities so that its benefits can be further enlarged. There should be a minimum of 10 pharma units (including Bulk Drug, Medical Device, Ayurvedic, Unani and Cosmetics Units) serving as members of 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 and submitted to the Department. 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 20.00 crore per cluster or 70% of the cost of project whichever is less. 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) 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.
- (iii) Assistance for engaging engineers and other experts for execution of civil works shall not exceed 5% of the Grant in Aid.
- (iv) 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 GoI 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 GoI assistance.
- (v) 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. The Scheme Steering Committee (SSC) would decide on the issue keeping the impetus to be given to the production of the products manufactured in the premises of SPV.
- (vi) Funds will be released in instalments depending upon the implementation plan, requirements of funds and as approved by the Scheme Steering Committee (SSC).

(7) 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) It shall be the responsibility of the SPV to bring in land as its contribution;
- (iii) 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.

(8) 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.

(9) 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 and Central Government and R&D organization. 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 pharma units (including Bulk Drug, Medical Device, Aurvedic, Unani and Cosmetics Units) as its shareholders.
- (iii) 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.

- (iv) 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.
- (v) No dividends are to be declared by the SPV-rather the profits are to be ploughed back into the SPV.
- (vi) 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.
- (vii) 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.

(10) 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 them to form 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 selection of agencies/ experts for various services such as capacity building, business development, technical, engineering, etc.;
 - (g) 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.;
 - (h) Provide other need based advisory services to the SPV in effective implementation of the scheme;
- (iii) PMC will be selected by the Department on nomination basis. The fee to the PMC would be separate from the grant being given to projects and will be met from “CDP-PS” Head.

(11) 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 on expeditiously.

(12) Implementation Framework

Scheme Steering Committee (SSC)

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 CDP-PS.

The composition of the Steering Committee will be as follows:-

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

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.

(13) 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 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.

(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 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.

(14) 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) in the following manner:-

Instalment	Percentage of Funds	Remarks/ Pre-requisite
1	30	<ul style="list-style-type: none">• mobilization advance against an Indemnity Bond, on final approval of the project by SSC
2	30	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• SPV has mobilized and spent its entire share in proportion to grant

The SPV shall submit the Utilisation Certificate (UC) for the amounts utilized as per the format in accordance with GFR 12A;

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

(15) 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.

(16) Miscellaneous Provisions

16.1 Monitoring and Management Expenses: Project monitoring and management expenditure will be limited to maximum 1% of the total budget outlay of the sanctioned funds will be utilised. The main activities for which these funds will be utilized include, mainly in DoP:-

- (i) Preparation of panels of Pharma Regulatory Affair Experts/Agencies for preparation of Detailed Project Report for assistance for eligible activities in the Pharma Clusters.
- (ii) Expenditure involved in site visits of the Pharma Clusters for monitoring of progress and evaluation of the scheme.
- (iii) Development of customized software for data management, specialized reports, monitoring and evaluation.
- (iv) CDP-PS related publicity material for awareness generation, workshops etc.
- (v) Organization of meeting of various Committees including the Scheme Steering Committee(SSC).
- (vi) Purchase of office automation equipment like photocopier, maintenance etc.
- (vii) Outsourcing of Data management services.

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(D) Pharmaceutical Promotion and Development Scheme (PPDS)

1.0 Objectives of the Scheme:

The objective of Pharmaceutical Promotion Development Scheme (PPDS) is promotion, development and export promotion in Pharmaceutical sector by extending financial support for conduct of seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector. Under PPDS the Department of Pharmaceuticals on its own or through financial support by way of Grant-in-aid to the Institutions, organizations, Voluntary organizations or Non-Government Organizations as mentioned in Rule 228 of GFR 2017,

- i. Conduct Training/knowledge improvement programs/activities on issues/subjects relevant to growth of pharmaceutical industry. An indicative list of subject is as under:-
 - a. Quality Management System/Quality Improvement Program
 - b. Handling USFDA notice
 - c. Success Story Presentation-Pharmaceutical Entrepreneur
 - d. Government regulations/guidelines for clinical trials in India versus USA, EU etc.
 - e. Waste Management
- ii. Organize Summits, Conventions, Exhibitions, Pharmacy weeks, meetings etc. in India and abroad and produce promotional materials like films, displays etc.
- iii. Conduct research studies, sector reports etc.
- iv. Purchase books, quality standards, pharmacopoeias, magazines, directories, software for developing information data banks, developing e-learning modules etc.
- v. Give awards to achievers in pharmaceutical industry.
- vi. For creating awareness and publicity of important activities related to Pharmaceutical/ Medical Device and related sector.
- vii. For any other activity not covered under above categories which may be decided by the Department of Pharmaceuticals from time to time.

2.0 Training/knowledge improvement programs/activities on issues/subjects relevant to growth of Pharmaceutical/ Medical Device and related sector

2.1 Objectives

- i. Conduct Training/knowledge improvement programs/activities on issues/subjects relevant to growth of pharmaceutical industry. An indicative list of subject is as under:-

- a. Quality Management System/Quality Improvement Program
 - b. How to handle USFDA notice?
 - c. Success Story Presentation-Pharmaceutical Entrepreneur
 - d. Government regulations/guidelines for clinical trials in India versus USA, EU etc.
 - e. Waste Management
- ii. Organize Summits, Convention, Exhibitions, Pharmacy week, meetings etc. in India and abroad and produce promotional materials like films, displays etc.

2.2 Eligible Organizations

The Department of Pharmaceuticals on its own or through financial support by way of Grant-in-aid to the Institutions, organizations, Voluntary organizations or Non-Government Organizations as mentioned in Rule 228 of GFR 2017, may organize such events. Government/Academic Bodies, National/State level Industries Associations like FICCI, CII, ASSOCHAM, PHD Chamber of Commerce are also eligible for conducting such events.

2.3 Criteria

The organization should ensure that the target group of participants is from Pharmaceuticals, Medical Devices and its related sectors.

2.4 The broad levels of financial support would be as follows:

S. No.	Category of event	Percentage Grants-in-aid support
1.	For programmes being organized by Government Departments /Institutions /Agencies, full funding may be provided	100% (that the grant-in-aid is worked out on the basis of thorough objective and realistic assessment of requirement in each case)
2.	Autonomous bodies, private agencies, industry associations, private institutions, NGOs and others. Activities organized on the initiative of the Department or on subjects suggested by the Department.	Not more than 75%
3.	Activities organized by autonomous bodies, private agencies, industry associations, private institutions, NGOs and others above on their own initiative and having relevance to the mandate of the Department.	Not more than 50%

4.	Mega events viz. India Pharma and India Medical Expo and other International events organized jointly by Department of Pharmaceuticals	The Grant-in-aid will be worked out based on the estimates furnished and the parameters like expenditure incurred in the past by organizers etc with the concurrence of IFD/Department of Expenditure etc.
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Note:

- (i) The organization should agree to the participation of at least one or two Technical/Administrative officer(s) from Department of Pharmaceuticals including one from concerned division free of charge as full delegates
- (ii) Under no circumstances, funds would be released to an Event Manager.
- (iii) Funds released shall not be for any activity of recurring nature
- (iv) The Department's fund will not be used for providing boarding/lodging, travel of speakers and delegates

2.5 Release of Grant

The Grant in aid will be released on submission of the following information/documents in the proscribed proforma (**Annexure-I**)

- (i) Request at least two months prior to the date of event.
- (ii) Confirmed date of the event / programme.
- (iii) Disclosure of sources of funding.
- (iv) Confirmation from the organizers that no Utilization Certificate is pending submission by them in respect of previous grant(s), if any, availed from this Ministry.

2.6 Documents /information required to be furnished by the agencies after successful organization of the events

The following documents should be furnished after organization of events:

- i. Proceedings of the event.
- ii. Copies/cutting of advertisements/publicity done.
- iii. List of participants.
- iv. List of resource persons with topics/presentations by them.
- v. Suggestions/Queries of participants, if any.
- vi. Outcome of the event / recommendations for various stakeholders.
- vii. Performance -cum- Achievement Report
- viii. Follow up action taken / to be taken.
- ix. Utilization Certificate (UC) in the proforma signed by the Head of the Organization.

3.0 Use of Logo support and keynote address by Minister/MOS/Secretary etc

Request for Logo Support of the DOP, inauguration /delivery of keynote Address by the Minister/MOS/Secretary /other senior Officers of DOP, Co-sponsorship by DOP without financial commitment, participation by officers of the Department as delegates should be specifically mentioned in the proposal clearly indicating profile of the organizations, performance of the past event, salient features of the current event, participants details, list of speakers and other relevant information. Specific prior permission of the Department should be obtained by the event organizers for the use of Logo of the Department in the pamphlets, brochures, banners, in the dais etc.

4.0 PARTICIPATION OF THE DEPARTMENT ON ITS OWN IN THE FAIRS /EXHIBITIONS / SEMINARS/CONFERENCES/ WORKSHOPS ETC

Organization of seminars /workshops / conferences/ participation in the fairs /exhibitions etc by the Department on its own, shall be made either through its own officers or through PSUs / NIPERs, Event Management Agency selected, short listed and empanelled after following due procedure through a transparent process. These events should be for promotion, development and export promotion in pharmaceutical, Bulk Drug and Medical Device sectors.

5.0 STUDIES / SURVEYS / ONLINE SURVEYS / MAGAZINES ETC

5.1 Objectives

DOP may provide financial assistance for conducting research studies, sector reports purchase of books, quality standards, pharmacopoeias, magazines, directories, software for developing information data banks, developing e-learning modules etc. to promote Pharmaceuticals and Medical Device sectors.

5.2 Eligible Organizations:

The Department of Pharmaceuticals on its own or through financial support by way of Grant-in-aid to the Institutions, organizations, Voluntary organizations or Non-Government Organizations as mentioned in Rule 228 of GFR 2017 organize such events. Government/Academic Bodies, National/State level Industries Associations, like FICCI, CII, ASSOCHAM, PHD Chamber of Commerce, NGOs etc., are also eligible to seek assistance for organizing seminars/workshops etc.

5.3 Criteria

Study/Survey must be useful in monitoring/reviewing/assessing and revising various schemes/plans/vision for the DOP as well as allied sectors.

5.4 Pattern of Assistance:

S. No.	Category of Study/Survey etc.	Percentage Grants-in-aid support
1.	For studies commissioned or purchases of sector reports from reputed organizations/institutions made by Government Departments /Institutions /Agencies,	100%
2.	For purchases of sector reports from reputed organizations/institutions made by autonomous bodies, private agencies, industry associations, private institutions, NGOs and others on the initiative of the Department or on subjects suggested by the Department.	Not more than 75%
3.	For purchases of sector reports from reputed organizations/institutions made by autonomous bodies, private agencies, industry associations, private institutions, NGOs and others above on their own initiative and having relevance to the mandate of the Department.	Not more than 50%

5.5 Release of Grant

The grant for studies commissioned and purchases of sector reports from reputed organizations/institutions will be released in three installments as per the following terms of payment:-

- i. 30 % will be released as advance after signing of the MOU by both the parties concerned and after executing a surety bond in the prescribed format on a Rs. 100/- stamp paper duly signed by the obligers, 2 sureties and 2 witnesses.
- ii. 30 % will be released on submission of the draft report along with executive summary.
- iii. 40 % will be released on submission and acceptance of the final report (10 hard copies and CDs) by DOP.
- iv. The exact terms and conditions of release of grant may not be specified, as the same may vary from case to case.

6.0 DOP may institute awards to achievers in pharmaceutical industry.

7.0 For any other activity not covered under above categories which may be decided by the Department of Pharmaceuticals from time to time.

8.0 The Secretary, Department of Pharmaceuticals may, in certain cases, permit or condone the departure from these guidelines to the extent he deems necessary in consultation with the Financial Adviser.

9.0 To whom application has to be addressed

The DOP will invite proposals in the last quarter of a financial year for the next financial year and a calendar of events to be supported during the year will be drawn and the concerned organization will be intimated for submitting their proposals as per the procedure. DoP will consider further applications, not listed in the above calendar subject to availability of funds.

All requests should be made to the Joint Secretary (Policy), Department of Pharmaceuticals, Shastri Bhavan, New Delhi. Website <http://pharmaceuticals.gov.in>

Application form for seeking financial support by Industry Associations/other organization under Pharmaceutical Promotion Development Scheme (PPDS) for conducting of Seminar/Symposium/Workshop/Conference etc.

I. DETAILS OF APPLICANT ORGANIZATION

1. Name of the organization with address, phone No./fax/Email	
<p>2. a) Legal status of the organizing institution (Please give details whether a trust, a company, registered society, educational institution, research organization, professional body involved in scientific/ academic/technical activities)</p> <p>b) Category of the Organization:</p> <p>i) Autonomous Body</p> <p>ii) Non-Government Organization (NGO)</p> <p>iii) Co-operative Society and Co-operative Institution</p> <p>iv) State Government/U'T</p> <p>v) Others</p>	
<p>3. i) In case of registered organization/society, please give details of registration No., place of registration and registration authority (enclose copy of the relevant documents).</p> <p>ii) Please confirm whether your organization has been operating for 3 years. If yes, please enclose list highlighting substantive achievements</p>	

II. DETAILS OF EVENT

4. Name/ Title of the Event:	
5. Level of the seminar/symposium/workshop i.e. whether Regional/National/International. Please furnish details of collaborating institutions, experts and participants	

6. Proposed dates of the Seminar/Symposium/Workshop. (Please enclose copy of detailed program)	
7. Full Address of the Venue for the Conference	
8. Brief objectives of the event including the topics to be discussed and the relevance of importance of the event in the national or international context.	

III. FINANCIAL DETAILS

9. Details of the budget estimate of the expenses for the Seminar along with income expected to be generated from registration fee from delegates, advertisements etc.	
10. Total estimates of Expenses (Details in separate sheet) (i) Total estimates of income (ii) Details of financial support from other organizations.	
11. Amount of financial assistance required from DOP	
12. Name & Address of the person(Head of the organization) responsible for furnishing Utilization Certificate (UC) certified by Chartered Accountant within 15 days of the completion of the event (phone number & email address should also provided).	

IV DETAILS OF FINANCIAL ASSISTANCE RECEIVED EARLIER

13. a) Whether any grant/financial support for Seminar/Symposium/Workshop/Conference etc. received earlier from DoP. If yes, please mention amount received b) Whether Utilization Certificates for grants for past events have been submitted (please give letter no. and date along with copy). If not, the reasons thereof.	
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V DETAILS OF PARTICIPANTS

14. No. of participants (along with list of speakers and experts)	
15. If foreign participants are being invited, whether applications submitted to Ministry of External Affairs for Political clearance or clearance obtained (please attach copy). No travel expense should be committed beforehand	
16. Whether clearance of Ministry of Home Affairs from Security angle in case of foreign participants has been obtained or applied for (please attach copy)	

VI UNDERTAKING BY THE HEAD OF THE INSTITUTION

It is certified that the information given in the proposal is true to the best of my knowledge.

On behalf of _____ (Name of Organization), I hereby undertake to ensure smooth conduct of the event, proper use of Government fund, and submission of utilization certificate and audited statement of accounts, within prescribed time limits. I also undertake to return the grant within 15 days to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, New Delhi in the event of failure to conduct the event on the date (s) indicated above or any deviation made from the commitments or furnishing of false information.

Name, designation &
Full contact details of
representative of
applicant organization

Place:

Date:

Seal of the Institution

Application Form for Financial Assistance for Conduct of Studies/Surveys/purchase of books etc.

(1) Name of the Organization

Address

Telephone/fax/E-mail nos.

(please attach copies of Registration certificate.

Memorandum and Articles of Association

And audited annual accounts for the last three years)

(2) Main activities of the organization

(3) Purpose and subject of the study/report etc.

(4) Methodology to be adopted

(5) Detailed terms of reference

(6) Benefits from the proposed study/report etc.

(7) Time for completion of the study & Implementation schedule

(8) Cost of the study along with detailed break-up.

(9) Amount of assistance sought from DOP

(10) Payment Schedule

(11) Whether Utilization Certificate for earlier Grants-in-aid received from DoP has been furnished.

(12) Enclose technical bio-data of Consultants Proposed to be engaged for the project.

Date: _____

**Signature
(Stamp)**

E. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

1. Background/Rationale

The sub-scheme is aimed at providing interest subvention to the eligible Small and Medium Scale Pharma Units having GMP compliant manufacturing facilities both for Bulk Drugs and Pharmaceutical Formulations. The eligible units intending to upgrade their manufacturing infrastructure to attain WHO-GMP norms, have to secure loan from any Financial Institution for upgrading their infrastructure and technology.

2. Goal of the Scheme

To facilitate Small and Medium Pharma Enterprises (SMEs) of proven track record to migrate from Schedule M to World Health Organization (WHO)/Good Manufacturing Practices (GMP) norms to enable them to participate and compete in global markets and earn foreign exchange.

2.1 Coverage: With the budgetary allocation of Rs. 144 crores for 2018-2020, it is possible to extend benefit of interest subvention to around 250 Pharma SMEs.

3. Scheme: Objective and details

3.1. Objective: The Scheme aims at providing assistance as **interest subvention** against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private Sector.

3.2. Scheme details:

a) Implementation Agency: The Scheme is implemented through a Public Sector Financial Institution (PSFI) to be identified by the Government. The Financial Institution will be selected through a process of open Competitive Bidding amongst the eligible Public Sector Financial Institution (PSFI). The framework for selection of the operating PSFI will be based upon competitive bidding in line with Expression of Interest (EoI) to be invited through adequate publicity as mandated for such activities.

b) The upper limit of interest subvention on loans for technology/infrastructure upgradation shall be restricted to 6% per annum for a period of three years on reducing balance basis. The maximum loan eligible for this purpose will be Rs. 4 crore, availed by the concerned SME for purpose of Upgradation to WHO-GMP norms.

c) Performance condition: The scheduled commercial bank/financial institution extending loan for assistance under this scheme shall ensure that:-

- (i) All beneficiary Pharma SMEs, to whom benefit of interest subvention is to be extended, must obtain WHO-GMP certification within 2½ years from the date of first disbursement of loan.
- (ii) Pharma SMEs which availed the benefit under the Scheme must achieve incremental export revenue in excess of the sanctioned loan amount, within 36 months of the last drawl of the loan, failing which loan will be converted into a normal loan by the Financial Institution. The interest subvention amount credited to the loan account with the

sanctioning commercial bank/financial institution will stand withdrawn along with penalty to be decided by the SSC.

4. Eligible activity: The scheduled Commercial Banks extending loan for Pharma SMEs to be eligible for interest subvention under the scheme need to consider the following infrastructure as eligible for approaching PSFI for assistance under the scheme:-

- a) Only machinery and electronic Management Information System (MIS) required for upgrading a schedule M plant into a WHO-GMP i.e., machinery to meet the gap only are to be considered.
- b) An indicative list of such equipment categories as provided by the Office of the DCGI is attached (**Appendix**). This list would be updated from time to time, based on the recommendations of DCGI (CDSCO), depending on the requirement of the Pharma industry under the WHO-GMP norms.
- c) Under the Scheme, procurement of only new machinery will be permitted.

5. Publicity Campaign & source of funds:-

The identified and selected Financial Institution will be responsible for undertaking awareness campaign in the Pharma SME clusters in partnership with Indian Drugs Manufacturers Association (IDMA), Bulk Drugs Manufacturers Association (BDMA) and Pharmexcil and respective State Governments / Drug Controllers. The objective is to create both awareness and to identify eligible and interested Pharma SMEs, besides creating demand for successful implementation of Scheme.

6. Performance Management/ Monitoring and Evaluation:-

6.1. Monitoring:-

- a) The operating PSFI will provide full access to Scheme monitoring portal to the Department of Pharmaceuticals for monitoring purpose.
- b) The Financial Institution will also furnish monthly information in respect of sanction and disbursement of interest subvention to the lending banks/financial institution towards the loans account of beneficiary Pharma SMEs and other related information to DoP.
- c) The operating PSFI will submit a quarterly progress report / statement indicating all Key Performance Parameters including the following:-
 - (i) Number of awareness events organized in Pharma clusters in partnership with IDMA, BDMA and Pharmexcil.
 - (ii) Number of applications pending sanction of interest subvention amount for more than 20 days.
 - (iii) No. of days taken to decide sanction/ no sanction
 - (iv) No. of days taken to disburse the sanctioned interest subvention against loans extended by the commercial banks/financial institution to eligible Pharma SMEs for technology/infrastructure upgradation under this scheme.
- d) The annual account pertaining to funds allocated to PSFI by DoP would be got audited by the operating Financial Institution by a Chartered Accountant and the report would be submitted to D/o Pharmaceuticals for review by the Scheme Steering Committee(SSC).

6.2. Management by Scheme Steering Committee (SSC)

A Scheme Steering Committee would be constituted to lay down norms for monitoring and for effective implementation of the Scheme.

The composition of the Steering Committee will be as follows:-

- (i) Secretary, DoP - Chairperson
- (ii) Financial Adviser, DoP-Member
- (iii) Joint Secretary, MSME- Member
- (iv) Joint Secretary, DIPP- Member
- (v) DCGI, CDSCO- Member
- (vi) CMD of identified Public Sector Financial Institution- Member
- (vii) DG, Pharmexcil- Member
- (viii) President, IDMA- Member
- (ix) President, BDMA- Member
- (x) Joint Secretary(Policy), DoP- Convenor

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

Functions:-

1. To review the Scheme quarterly and give a direction to the Scheme.
2. To take all decisions required for successful implementation of the Scheme, including modifications if any required.
3. It shall hold meeting once in 3 months.
4. Joint Secretary (Policy), Nodal officer of the Scheme and Secretary (Pharma) are jointly empowered to resolve issues in the implementation of Scheme in the interest of the Scheme mandate, where organizing the meeting of SSC may cause delay and affect its implementation.

7. Mid-term review of the Scheme

A mid-term review of the Scheme would be conducted immediately after completion of 1 year of the launch of the Scheme. For this purpose, D/o Pharmaceuticals will engage the services of institutes of repute such as National Council for Applied Economic Research or any other independent agency for conducting the said review. The review report would be submitted to the Scheme Steering Committee for taking a view on continuation/ amendment of the Scheme.

8. The Primary Lending Institutions (PLIs) can register with the operating financial institution by signing MOU.

9. The selected PSFI to operate the scheme shall be responsible for ensuring proper implementation and monitoring of the scheme and will put in place appropriate mechanisms for the purpose. The PSFI will provide periodic monitoring inputs to Department of Pharmaceuticals through regular monthly and quarterly reports.

10. Miscellaneous Provisions

10.1 Monitoring and Management Expenses: Project monitoring and management expenditure will be limited to maximum 1% of the total budget outlay of the sanctioned funds will be utilised. The main activities for which these funds will be utilized include, mainly in DoP:-

- (i) Preparation of panels of Pharma Regulatory Affair Experts/Agencies for preparation of Detailed Project Report for upgradation of technology and infrastructure relevant for attaining WHO-GMP norms.
- (ii) Expenditure involved in site visits of the beneficiary of Pharma SMEs for monitoring of progress and evaluation of the scheme.
- (iii) Development of customized software for data management, specialized reports, monitoring and evaluation.
- (iv) PTUAS related publicity material and awareness generation.
- (v) Organization of meeting of various Committees including the Scheme Steering Committee(SSC).
- (vi) Purchase of office automation equipment like photocopier, maintenance etc.
- (vii) Outsourcing of Data management services.

**EQUIPMENT CATEGORIES REQUIRED FOR UPGRADATION
A PHARMA PLANT FROM SCHEDULE M TO WHO-GMP NORMS***

Eligible activity	Formulation Plant	API/ Intermediate/ Bulk Drug Plant
1. Up gradation of HVAC (<i>Heating, Ventilation, and Air Conditioning</i>) system to WHO norms i.e. HEPA (High-Efficiency Particulate Air filters) etc	√	√
2. Stability testing chambers.	√	√
3. All equipment & instruments for operating a Microbiology laboratory including autoclaves, incubators, biosafety cabinets, colony counters, HVAC systems	√	√
4. All lab scale and pilot scale manufacturing equipment required for R&D development - formulation/bulk	√	√
5. State-of- art lab equipment for testing as per Pharmacopeia other than IP not limiting to NMR, HPLC, HPTLC, IR Spectrophotometer, Atomic Absorption Photometers, GC, Electrophoresis and Dissolution apparatus	√	√
6. Water management and purification systems including Steam systems.	√	√
7. Automatic particle counters for sterile areas	√	√
8. Laboratory information management system	√	√

* The list is subject to requirements/changes in WHO-GMP regulatory compliance to be informed/ provided by DCGI from time to time.

Note: The required renovation of factory building is not included in the project cost to be financed.
