

Dated: 27th July, 2020

Guidelines of the Scheme “Promotion of Medical Devices Parks”

1. Background

- 1.1 The Medical Device industry is highly capital intensive with a long gestation period and requires development and induction of new technologies. It also requires continuous training of health providers to adapt to new technologies. Most of the hi-tech innovative products originate from a well-developed eco-system and innovation cycle which is yet to be fully developed in India. The industry depends on imports up to an extent of 86%.
- 1.2 Since the creation of testing and laboratory facilities requires huge investment, a Scheme called “Promotion of Medical Device Parks” has been approved by the Government of India on 20th March 2020. The parks will provide common testing and laboratory facilities/ centre at one place reducing the manufacturing cost significantly and create a robust ecosystem for medical device manufacturing in the country.
- 1.3 The Scheme has been notified vide Gazette notification no. - 31026/08/2020-MD, dated - 21/07/2020.

2. Objective

- 2.1. Creation of world class infrastructure facilities in order to make Indian medical device industry a global leader.
- 2.2. Easy access to standard testing and infrastructure facilities through creation of world class Common Infrastructure Facilities for increased competitiveness will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market.
- 2.3. Exploit the benefits arising due to optimization of resources and economies of scale.

3. Definitions

- 3.1. **Common Infrastructure Facility (CIF):** The Common facilities with capacity commensurate with the expected number and type of medical device manufacturing units in the park. Some of the indicative activities under the Common facilities/centres are:
 - i. Component Testing Centre/ESDM/PCB/Sensors facility
 - ii. Electro-magnetic interference & Electro Magnetic Compatibility Centre

- iii. Biomaterial / Biocompatibility /Accelerated Aging testing centre
- iv. Medical grade moulding/milling/injection moulding/machining/tooling centre
- v. 3D designing and printing for medical grade products.
- vi. Sterilization/ETO/Gamma Centre
- vii. Animal Lab and Toxicity testing centre
- viii. Radiation testing centre, etc.
- ix. Radiology Tube/Flat Panel Detectors/MRI Magnets/ Piezo electrical crystals/power electronics facility
- x. Solid waste management/ETP/STP/Electronic Waste management unit
- xi. Common Warehouse & Logistics (Clearing and Forwarding, Insurance, Transportation, Customs, Weighbridges, etc.) centre
- xii. Emergency Response Centre/Safety/Hazardous Operations audit centre
- xiii. Centre of Excellence/Technology Incubator/ ITI/Training Centres

Note: The facilities/centres required are constantly evolving and include laser, tool rooms for mechatronics, etc. The list of common facilities/centre given above is indicative and states are encouraged to plan for facilities, the implementing agency considers useful.

3.2. **Medical Device Park:** For the purpose of this Scheme, a Medical Device Park means a designated contiguous area of land with common infrastructure facilities for the exclusive manufacturing of medical devices.

3.3. **Project cost:** The cost of establishing CIF in the Medical Device Park.

3.4. **Proposer:** The proposer for the purpose of the Scheme shall be a State Government.

3.5. **State:** State or Union Territory of Republic of India.

4. **Scope of the Scheme**

4.1. This is a Central Sector Scheme.

4.2. Total financial outlay of the Scheme is Rs. 400 Crore.

4.3. Four Medical Device Parks will be supported under the Scheme.

4.4. Maximum grant-in-aid for one Medical Device Park will be limited to Rs 100 crore.

4.5. The duration of the Scheme is from FY 2020-2021 to FY 2024-2025.

4.6. Under the Scheme, a one-time grant-in-aid will be provided for creation of common infrastructure facilities in selected Medical Device Park proposed by a State Government.

4.7. The Scheme will be implemented through a State Implementing Agency (SIA), a legal entity, set up by the concerned State Government.

4.8. The grant-in-aid will be 70% of the project cost of the common infrastructure facilities. In case of North Eastern States and Hilly States (i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), the grant-in-aid will be 90% of the CIF.

5. **Project Management Agency (PMA)**

5.1. A Project Management Agency (PMA) will be nominated by Department of Pharmaceuticals (hereinafter referred as DoP) for providing secretarial, managerial and implementation support to DoP for effective implementation of the Scheme.

5.2. The PMA would be responsible for:

- i) Preliminary examination of the proposals received from states and seeking additional information including documents from states, if required for completeness of the proposals.
- ii) Appraisal of proposals and making appropriate recommendations to the Scheme Steering Committee (SSC) for approval of proposals under the Scheme.
- iii) Appraisal of DPRs including financial viability, commercial sustainability and socio-economic impact of the projects.
- iv) Assisting DoP in periodic monitoring of the projects and timely disbursement and utilisation of the funds.
- v) Monitoring Medical Device Park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (CPM) and Gantt Chart and periodic submission of the report to SSC.
- vi) Monitoring event report at every stage, an ex-post activity chart with complete breakdown of activities, the original expected dates and actual dates along with the flow of fund requirements
- vii) Periodic physical inspection of the Medical Device Parks.
- viii) Any other matter pertaining to the Scheme assigned by DoP.

6. **Technical Committee (TC)**

6.1. A Technical Committee, constituted by the DoP will assist SSC in discharging its functions. TC will provide comments on any technical matter referred to by the DoP/ SSC.

6.2. Technical committee shall comprise of three experts having knowledge and experience in regulations, manufacturing of medical devices and R&D of medical

devices. Out of three, one expert having experience in implementation of infrastructure projects related to development of industrial park/ zone.

7. State Implementing Agency (SIA)

7.1. State Implementing Agency (SIA) shall be a legal entity (with minimum 51% equity shareholding of State Government in the paid-up capital of SIA) set up by the State Government for the purpose of implementing the Medical Device Park Project.

7.2. SIA shall be responsible for day to day management of Medical Device Park.

7.3. The SIA shall be responsible for:

- i) Preparing the Detailed Project Report (DPR) covering the technical, financial, institutional and operational aspects of the CIF project of the Medical Device Park.
- ii) Ensuring and making available balance amount of the Project Cost.
- iii) Obtaining all statutory approvals / clearances including all environmental clearances.
- iv) Providing single window system for various approvals and testing certificates.
- v) Recruiting suitable professionals in order to ensure that the project is executed smoothly.
- vi) Implementing various interventions as outlined and approved in DPR.
- vii) Preparing event report at every stage, an ex-post activity chart with complete breakdown of activities, the original expected dates and actual dates along with the flow of fund requirements as specified in DPR.
- viii) Furnishing regular progress reports of the project to DoP/ PMA.

7.4. SIA shall allot land only on long term lease basis.

7.5. SIA shall keep a provision for cancellation of allotment of the land, if the commercial production is not started by the allottee within a period of two years from the date of allotment order unless it extends the time period by one year on valid reasons.

7.6. SIA shall submit any report sought by DoP, from time to time.

8. Role of State Government

8.1. State Government shall be responsible for:

- i) Submission of Project Report.
- ii) Land: State Government will be responsible for providing encumbrances free land for the development of the Medical Device Park.

- iii) Ensuring and making available balance amount of the Project Cost through budgetary and / or other sources.
- iv) Obtaining all statutory approvals / clearances including all environmental clearances.
- v) Providing single window system for various approvals and testing certificates.
- vi) Providing necessary infrastructure such as access road, power, water supply, etc. up to the park.
- vii) Providing all project related clearances expeditiously.
- viii) Providing all clearances required by individual medical device units expeditiously.
- ix) Promoting the Medical Device Park at National & International level.
- x) Provide 33KV electricity supply lines and 1500 KLPD water supply lines with the necessary infrastructure up to the project site.

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

9.1. The proposals under the Scheme will be approved by the Scheme Steering Committee (SSC) constituted by DoP.

9.2. The composition of the SSC is as follows:

- a) Secretary, DoP - Chairperson
- b) Financial Adviser, DoP - Member
- c) Joint Secretary, Ministry of Environment, Forest and Climate Change - Member
- d) Joint Secretary, Department for Promotion of Industry and Internal Trade - Member
- e) Joint Secretary, Department of Health and Family Welfare – Member
- f) DCGI, Central Drug Standard Control Organisation - Member
- g) Joint Secretary(Policy), DoP - Convenor

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

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

9.4. The SSC will be assisted by the Project Management Agency (PMA).

9.5. The SSC will meet as often as necessary to ensure timely consideration of proposals and release of instalments of grant-in-aid and to review progress of the

projects under the Scheme. However, it shall hold meeting at least once in 6 months.

10. Proposer

- 10.1. A State Government can make only one proposal of Medical Device Park under this Scheme.
- 10.2. The proposed park shall not be less than 150 acres in area. For North Eastern States and Hilly States (i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), the area of proposed park shall not be less than 100 acres.
- 10.3. At least 50% of the total area of the Medical Device Park shall be made available for allotment to individual medical device units.
- 10.4. The proposer shall have to be in full possession of the land free of all encumbrances proposed for establishing the Medical Device Park on the date of submission of proposal.
- 10.5. The proposer shall submit a Project Report (PR) including the proposed cost of establishing the Medical Device Park including cost of CIF.
- 10.6. The project report shall cover feasibility study establishing viability of the Medical Device Park at the identified location. The feasibility study shall cover assessment of environmental risk and associated health risk, business risk and management risk.
- 10.7. Project cost shall not include the following:
 - I. Cost of Land,
 - II. Pre-operative expenses like preparation of Project Report,
 - III. Administrative and management support expenses.
- 10.8. The proposer shall give full details of the location of the proposed Medical Device Park including land area (in acres), location map and area map.
- 10.9. The proposer shall provide an undertaking for establishing a single window for all necessary clearances required for the manufacturing units located in the park.
- 10.10. The proposer shall submit an undertaking to establish a Research and Development facility as a Centre of Excellence in the park. Such facility may be operated by an institution or by a society. Such centre of excellence shall employ competent scientists with suitable experience and promote industry academia linkage. The State Government shall provide sufficient financial and other support for such centre.
- 10.11. The proposer shall submit an undertaking to ensure availability of funds.

10.12. The proposer may be required to make a presentation on the proposal before SSC.

11. **Proposal**

11.1. The State Government should identify a suitable location for establishment of Medical Device Park keeping in mind various factors viz., assured availability of power, assured availability of water, transport connectivity with railways, national highway, port, airport, environmental aspects etc. The identified location should be well away from the eco-sensitive zone of protected areas.

11.2. The proposer State shall submit an undertaking that it shall not increase the land lease rent and utility charges, as declared in the proposal, beyond 5% per annum, for the next 10 years.

11.3. The proposal under the Scheme shall be made within 60 days of issuance of these guidelines, in the format provided at **Annexure 1**.

12. **Selection of Proposal**

12.1. The evaluation criteria provided in **Appendix** of these guidelines shall be used for selection of States. The States obtaining top four ranks will be considered for selection under the Scheme.

12.2. In case, the selected State fails to submit the DPR in time or fails to implement the project as per the timelines stated in the DPR, the in-principle approval may be cancelled by the SSC. In such case, State in the ranking may be selected for the purpose of the Scheme.

13. **In-Principle approval under the Scheme**

13.1. PMA will evaluate the proposals and give its recommendations to DoP.

13.2. The recommendations of the PMA will be placed before SSC for its consideration.

13.3. After receiving in-principle approval from the SSC, DoP will issue a letter of in-principle approval to the selected States.

14. **Detailed Project Report (DPR)**

14.1. A Detailed Project Report (DPR) shall be prepared and submitted to DoP along with the details as per the format given in **Annexure 2** of these guidelines by the selected State Government within 180 days of date of issuance of in-principle approval letter.

14.2. The DPR shall include, among other things, the following details:

- a) Location of the proposed Medical Device Park
- b) Total land area of the park
- c) Total land area of the park available for the allotment to units

- d) Detailed breakup of the utilisation of the remaining land (Green belt, landscape, CIF, etc.)
- e) Project cost
- f) Number of projected medical device units
- g) Proposed time period for obtaining clearances from Central and State Government for establishing the Medical Device Park.
 - The time period for completing the CIF
 - The date at which the plots will be allocated to the medical device units
- h) Details such as brief description of the CIF, estimated capacity of CIF, justification for arriving at the capacity, cost of CIF, technology used, approximate time to establish the CIF, approval required from different agencies, projected time lines for obtaining approval, for each component of CIF based on the projected number of manufacturing facilities.
- i) Detailed viability of the project along with the operational cost and proposed user charges.
- j) Provide an analysis of occupational hazards in the park
- k) Indicative charges (not higher than those committed in the proposal) to be collected from the medical device manufacturing units:
 - land lease rate per sq. meter
 - Utilities charges:
 - Power,
 - Water,
 - Park maintenance charges
 - Warehouse charges.
 - Quality control testing charges
- l) Details of all the business processes of the Medical Device Park to identify impediments and bottlenecks and to draw action plan for enhancing competitiveness of the units to be set up in the Medical Device Park.
- m) Mode of funding and phasing of expenditure i.e. contribution of various stakeholders (Gol, State Govt. and others)
- n) Financial viability to the extent available i.e. Internal Rate of Return, % occupancy to achieve viability etc.
- o) Provide a Medical Device Park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (CPM) and Gantt chart.

14.3. Ceiling on the eligible cost of the project

- i. Assistance for Administrative and other management support of SIA for the project implementation period shall not exceed 5 % of the grant-in-aid.
- ii. Assistance for engaging engineers and other experts for execution of civil works shall not exceed 5 % of the grant-in-Aid.
- iii. No grant shall be given towards construction of roads, compound wall and buildings. However, as far as various scientific facilities/ centres are concerned, 30% of the estimated cost of respective facility/ centre will be allowed from grant-in-aid towards construction of the building.

15. Final approval under the Scheme

- 15.1. PMA will appraise the DPR and submit its recommendations to the SSC for its consideration.
- 15.2. After receiving final approval from the SSC, DoP will issue letter of final approval to the selected State.

16. Post Approval

- 16.1. The project shall be completed within two years from the date of release of the first instalment of the grant-in-aid, unless the period is extended by the SSC.
- 16.2. SIA shall furnish a quarterly progress report on the development of the park
- 16.3. PMA shall assess the progress of the project from time to time and submit the report to the SSC.

17. Release of funds

- 17.1. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds shall also be necessary before release of Central Government assistance.
- 17.2. Grant-in-aid will be released in four instalments in the following manner:

Instalment	Percentage of Funds	Remarks/ Pre-requisite
1 st	30	<ul style="list-style-type: none">• On final approval of the project by the SSC and after deposit of 30 percent of SIA's share in the project cost in the Trust and Retention Account (TRA) or Escrow or No Lien Account as the case may be, subject to the condition that all relevant environment clearances are in place.

Instalment	Percentage of Funds	Remarks/ Pre-requisite
2 nd	30	<ul style="list-style-type: none"> • 60% utilisation of the 1st instalment and after proportionate expenditure has been incurred by the SIA with proportionate physical progress of the Medical Device Park as per the DPR • Against the production of Bills
3 rd	30	<ul style="list-style-type: none"> • 100% utilisation of 1st instalment and at least 60% utilization of 2nd instalment and after the proportionate expenditure has been incurred by the SIA with proportionate physical progress of the Medical Device Park as per the DPR • Against the production of Bills
4 th	10	<ul style="list-style-type: none"> • 100% utilisation of 2nd and 3rd instalments • SIA has mobilized and spent its entire share in proportion to the grant and completed the project in all respects.

17.3. The SIA shall open a Trust and Retention Account (TRA) or Escrow or No Lien Account as may be decided by the SSC for the purpose of parking the funds received as grant-in-aid from the Central Government under the Scheme and also the State Government share.

17.4. The SIA shall submit the Utilisation Certificate (UC) for the amounts utilized as per the format prescribed in GFR.

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

18. **Maintenance / Ownership of Assets**

18.1. SIA shall be responsible for Operation and Management of assets created under the Scheme.

18.2. The assets acquired by the SIA out of Central government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.

18.3. A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by Central government should be maintained as per GFR.

18.4. If, for any reasons, SIA is liquidated, Government of India will have the first right to recover the grant-in-aid released for the project in case any surplus is left in the process of liquidation.

- 18.5. Escalation in the cost of project due to any reason, will be borne by the State government/ SIA. The Central government shall not accept any financial liability arising out of operation of any CIF.
- 18.6. For successful implementation and operation of the Medical Device Park, agreements shall be entered into between Government of India (GoI) and the State Government on one hand and between State Government and SIA on the other hand. The draft agreements will be circulated along with the final approval letter.
- 18.7. In addition to the CIF, the SIA and the State shall actively facilitate common services/utilities required for smooth running of businesses such as petrol pumps, banks, cafeteria, business centre, parking for trucks, convenience stores, medical service centre etc.
- 18.8. SIA shall constitute a management committee comprising of the representatives of the State Government, SIA, two representatives nominated from among the manufacturing units situated in the park and State Drugs Controller, for monitoring operation and maintenance of the park after completion of the project.



(Navdeep Rinwa)

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New Delhi, Dated: 27th July, 2020

Copy to:

1. All concerned Ministries / Departments of Government of India
2. All States / Union Territories
3. Cabinet Secretariat
4. PMO
5. NITI Aayog
6. Comptroller and Auditor General of India
7. AS&FA, Department of Pharmaceuticals
8. Industry Associations
9. Internal Circulation



(Navdeep Rinwa)

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Evaluation Criteria for Selection

S. No.	Marking Criteria	Maximum Marks
1	Utility charges (rates) as per proposal submitted by State Govt. (the State quoting the lowest rate will be awarded full marks and others will be rated pro-rata): <ul style="list-style-type: none"> i. Power (10) ii. Water (7) iii. Park maintenance charges (5) iv. Warehouse Charges (3) 	25
2	Policy incentives of state government applicable for Medical Devices Industry <ul style="list-style-type: none"> i. Interest Subvention Scheme (6) – (the State quoting highest percentage of interest subvention for a period of 10 years from the date of operation of the park, shall be awarded highest marks and others shall be rated pro-rata) ii. GST reimbursement, subsidy, incentive etc. against investment (6) - (the State quoting highest percentage of the reimbursement of investment, for a period of 10 years from the date of operation of the park, shall be awarded highest marks and others shall be rated pro-rata). 	12
3	Connectivity of the Park <ul style="list-style-type: none"> i. Air Cargo / Airport within 50 km from site (4) ii. National Highway within 25 km from site (4) iii. Sea Port / In-land waterway/ Dry port within 100 km from site (4) 	12
4	Lease rate to be offered to individual units of medical device to be set up in the park - the lease rent shall be compared based on the NPV of the upfront lease payment and/or periodic lease/ maintenance charges per sq. meter, discounted at SBI 1 Year MCLR applicable on the date of evaluation (the State quoting the lowest lease rent per sq. meter on NPV basis, shall be awarded full marks and others will be rated pro-rata).	10
5	Total area of the proposed park <ul style="list-style-type: none"> i. The hilly States, as defined in the guidelines, shall get 2.5 marks for every additional 35 acres. over and above 100 acres minimum stipulated land 	10

	ii. Other States shall get 2.5 marks for every additional 50 acres of land over and above 150 acres minimum stipulated land	
6	Uninterrupted 24*7 availability, with committed source and necessary infrastructure, of (Yes/ No): i. Power (4) ii. Water supply (3)	7
7	Full exemption of Stamp Duty and Registration charges (Yes/No)	5
8	Latest Ease of Doing Business Ranking of the State – The marks shall be awarded based on the slabs of ranking: i. Rank 1 to 5 = 5 Marks ii. Rank 6 to 10 = 4 Marks iii. Rank 11 to 15 = 3 Marks iv. Rank 16 to 20 = 2 Marks v. Rank 21 to 25 = 1 Mark vi. Rank below 25 = 0 Mark	5
9	Availability of Technical Manpower in the State i. No. of Engineering, Medical and Pharmacy colleges ≥ 30 (3) ii. No. of specialised research institutes in Medical Device sector ≥ 1 (2)	5
10	Presence of Institutes for technology transfer (Yes/No)	5
11	Industrial Network i. Ancillary spare part producers ≥ 50 (2) ii. Registered MSMEs ≥ 1000 (2)	4
	Total	100

Proposal Form

1. Instructions

- 1.1. The proposal shall be duly signed by the authorized signatory.
- 1.2. Proposers are advised to go through the guidelines carefully before submitting the proposal.
- 1.3. Proposers shall follow the format provided in this proposal form for submitting the proposals. Proposers shall provide information and enclose all the supporting documents as detailed.
- 1.4. All proposals will be submitted to the DoP in physical form and soft copy (pen drive/ CD) in a sealed envelope, addressed to Dr. Sumit Garg, Deputy Secretary (Policy), Department of Pharmaceuticals, Ministry of Chemical & Fertilizers, Room No. 228, A-Wing, Shastri Bhawan, New Delhi – 110001.
- 1.5. Proposal has following two sections:
 - I. Proposer Details
 - II. Details of the Proposal

2. Section I – Proposer Details

- 2.1 Name of the State
- 2.2 Authorised Signatory Details – Name, Designation, Contact No. (Mobile and Office Landline No.), Email and complete office address.

3. Section II - Details of the Proposal

3.1 Cost of Development of the Park & tentative source of funds (Rs. in crore):

- i. Cost of Development of the Park (estimated)
- ii. Central Government Share (Grant-in-Aid)
- iii. State Government /Union Territory share with source of funds for share of State Govt./ Union Territory

3.2 Details of Land: Total land area (in acres) of the proposed park and estimate of area available for allotment to medical device manufacturing units (which shall be not less than 50% of the total land area).

The State is required to furnish the details on the following specific points (in case, any of the following is applicable to the land, including part of the land, proposed for the park):

- a) Location of the land on google map, mapping of the land and land survey report
- b) Status of ownership, possession and mutation of the land in the revenue records
- c) Status of any encroachment, unauthorised possession or habitation on the land (including part of the land) proposed for the park
- d) Whether the land (including part of the land) is subject to any rehabilitation requirement etc. The status, procedure and timelines of the same should be clearly mentioned
- e) Whether there is any compensation related issue which is pending for the land (including part of the land)
- f) Whether there is any legal dispute or claim, pending in any court of law with any party for the land (including part of the land). If yes, detail about nature of dispute, forum where pending and any timelines for closure to be furnished.
- g) Any other known encumbrance, restriction or relevant information which may have an impact on timely completion of development of the Park, please furnish the details.

3.3 Land Lease Rate

Please specify the land lease rate (*annual rent per square meter in Rs.*) to be offered to medical device manufacturing units to be set up in the park. The state is required to clearly mention the upfront fee payable by the manufacturing unit and all subsequent payment with the periodicity and duration of payment.

The lease rent referred to above shall be a comprehensive levy for allotment of land.

3.4 Commitment to provide 24*7 availability of power and water supply

The State is required to give a commitment with broad details for sourcing continuous power and water supply, which shall be considered for the evaluation of the proposal. However, the selected States will be required to provide detailed justification and feasibility for sourcing continuous power and water supply in the Detailed Project Report.

3.5 Location of the park vis-à-vis connectivity

The State should specify the distance (in km) of proposed Park from the following:

- a) Nearest National Highway
- b) Nearest Air Cargo/ Airport
- c) Nearest Sea Port / In-land waterway/ Dry Port

Please specify the location and name the National Highway, Air Cargo and Nearest Sea Port/ In-land waterways and Dry Port.

3.6 Location of the park vis-à-vis eco-sensitive zone of protected area

Whether the land is in proximity to any of the eco sensitive zone of protected area. The state is required to furnish the detail of distance (in km) of proposed park from nearest such zone.

3.7 Policy incentives given/proposed by the State government for Medical Device industry

- a) **Interest subvention scheme:** Whether the State has/proposes any interest subvention scheme on the loan availed by the Medical Device manufacturing units. State is required to provide the detail of percentage of interest rate subvention for a period of 10 years from the date of operation of the park.
- b) **Incentive in the form of GST reimbursement, subsidy etc. against investment:** The State is required to submit detail of all incentives by way of GST reimbursement/ subsidy or any other form of incentive, as a % of the total investment made by Medical Device manufacturing unit. State is also required to submit the calculation of such % of incentive against investment.
- c) Whether State commits to exempt the Stamp Duty and Registration Charges for medical device manufacturing units (Yes/ No).

Please submit the relevant supporting documents.

3.8 Utility Charges

State is required to submit the following utility charges to be charged from Medical Device manufacturing units. The said charges will have to be committed by the State and undertaking in this regard shall be submitted as appended in this Proposal Form.

Utility	Units (for specifying the charges)
Power	kWh
Water	Per kilo litre
Warehouse	Monthly charges per square meter
Park maintenance charges	Annual charges per square meter

3.9 Availability of technical manpower

- a) Specialised research institutes in Medical device sector- Number, Name, Address and recognition status

- b) Engineering, Medical and Pharmacy colleges- Number, Name, Address and recognition status

Institute recognised by concerned State or Central body only shall be considered.

3.10 Number of Industrial Network in the State

- a) Ancillary spare part producers – Name and location of engineering ancillaries in the State
- b) Registered MSMEs – Name and location of engineering MSMEs in the State

3.11 Institutes for technology transfer

- a) Institute in the State involved in Technology Transfer

Document required: Such Institute's Registration Documents or Letter of Intent to State/ SIA to support the Park or MoU with the State.

3.12 Latest Ease of Doing Business ranking of the State

Undertaking

In connection with our application for development of a Medical Device Park as notified vide notification no. - 31026/08/2020-MD, dated - 21/07/2020 and guidelines thereunder, the State of acting through authorised signatory Sh..... do hereby undertake unconditionally and irrevocably that the State of shall ensure to:

- i) adhere to the roles and responsibilities of the State as outlined under these guidelines and fulfil all the commitments made in the proposal.
- ii) set up a State Implementing Agency (SIA) with the roles and responsibilities, as outlined in the Guidelines of the Scheme "Promotion of Medical Device Parks".
- iii) make available balance amount of Project Cost without any delay, as may be required for completion of development of Medical Device Park, through budgetary and/or other sources, as may be necessary.
- iv) not increase the land lease rent and utility charges, as declared in the proposal, beyond 5% per annum, for the next 10 years.
- v) establish a Research and Development facility as a Centre of Excellence in the park to be operated by an institution or by a society. Such centre of excellence shall employ competent scientists with suitable experience and promote industry academia linkage. The State Government shall provide sufficient financial and other support for such centre.
- vi) adhere to the responsibilities as specified in these guidelines and also the SIA, as appointed, and implementing agency, if any, as appointed, shall also adhere to the roles and responsibilities specified in these guidelines.

To be signed by the Authorised Signatory

Mention name and designation

Detailed Project Report (DPR)

1. The DPR should include the following information among other details.
2. **Proposed State Implementing Agency (SIA)** - Type of organisation, legal status, shareholding pattern (give detail of any private participation such as PPP agreement, MoU etc. with model terms and structure), functions and responsibilities, budgetary allocation (if any), administrative dept. of the State for SIA.
 - a. **Governing Body:** Constitution of governing body of the SIA.
 - b. **Key Personnel Details:** Contact details of three senior officials of the proposer. Details would include Name, Designation, Address, phone, email
 - c. **Contact Details of Authorized Representative:** Details would include Name, Designation, Address, phone, email

Documents to be furnished: all applicable documents.

3. **Description of the Park:**
 - a. Details of area of land allocated for Park, address and location
 - b. Land Acquisition details with Survey nos.
 - c. Any change in the status of encumbrance, pending legal dispute etc. submitted earlier in the proposal form
 - d. Connectivity and linkage (distance from the nearest National Highway, Airport, Sea Port, Railway Station, residential area, etc.)
 - e. Strength of the project location, description of the terrain, natural water resources available, type of land (forest, agriculture, etc.) and other relevant detail, if any.
 - f. Specify the useable land (Industrial Plots and plotting pattern based on number and size of plots), number of projected manufacturing facilities, internal roads, green buffer, open space, social infrastructure, support facilities and CIF.

Document to be furnished: Layout of the proposed Medical Device Park and Geotagging details

4. **Cost estimation & source of funds:**
 - a. Furnish detailed head-wise cost of:

- **Development of the Park:** Provide breakup of cost into land development, green belt, internal roads, sewage, culverts, RCC drains, compound wall, street lighting, support facilities & misc. Provide cost of each building proposed in the Park with purpose of such building.
 - **Development of CIF:** Provide break-up of cost of every project/ facility covered under common infrastructure facility.
- b. Give Source of funds under the following broad heads:
- Share of Central Govt. (grant-in-aid)
 - Share of State Govt. (Please specify details of Budgetary Allocation, Equity, Loan or any Other form of funding)
 - Other Source of funds – (Please specify the source as bank loans, public bonds, private participation etc.)
- c. Specify whether external funds, if any, shall be raised by the State of SIA and proposed model of fund raising.
- d. Give phase-wise disbursement schedule of funds from all the sources till completion of the Park.
- 5. Source of Revenue:** Furnish the detailed sources of revenue, with estimated annual revenue from each source.
- a. Budgetary Allocation from the State
 - b. Land lease
 - c. Utility Charges
 - d. Any other source of revenue envisaged

Revenue Head	Charge per unit	Annual Revenue (Rs. In crore)
Land Lease	per sq. meter	
Power	kWh	
Water	per kilo litre	
Warehouse	Monthly charges per square meter	
Park maintenance	Annual charges per square meter	
Any other	Specify nature and unit	

6. **Development of Common Infrastructure Facility (CIF):** The State is required to submit the detail for individual project item/ facility under CIF, as defined in the guidelines.
 - a. Brief description the project item/ facility,
 - b. Estimated capacity with detailed justification for arriving at such capacity considering area of the Park, proposed number of manufacturing units etc.
 - c. Cost of each project item/ facility
 - d. Comment on the technology applied with technical feasibility
 - e. Timelines for starting the construction and completion of individual project item/ facility
 - f. Phasing of individual project item/ facility, based on the estimated allotment of land to manufacturing facilities

7. **Infrastructure Support by the State:** The DPR should contain the following for support infrastructure to be provided by the State with timelines of completion:
 - a. **Power & Water:** Detailed plan for committed source of water and power supply with capacity and adequacy to support the size of park and projected number of manufacturing units. Provide details of any necessary infrastructure to be created by the State like sub-station, transmission line, dedicated water reservoir and pipe-line etc. with timelines.
 - b. **Ancillary Infrastructure:** All ancillary infrastructure like road, sewage, sanitation and social infrastructure to be developed by the State. Give size and scale of such ancillary infrastructure and proposed timelines of completion.

8. **Schedule for completion of the Park**
 - a. Provide the Park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (CPM) and Gantt Chart including financial expenditure plan for each activity with proposed starting and completion date.
 - b. Provide the "Schedule Date of Commercial Operations of the Park".

9. **Single Window Mechanism:**
 - a. Provide details of single window mechanism proposed to be set-up in the park for giving clearance to the manufacturing units.
 - b. Mention if any clearance under the proposed single window mechanism is to be given by Central Govt.

- c. Provide details, if any clearance is not proposed to be kept under the single window mechanism and the reason for the same.

10. Financial viability of the Park:

- a. Provide detailed market survey with respect to existing status of pharmaceutical sector in the State, strategic and locational advantage of the Park for new investment, policies of the State Govt. to attract FDI/ Domestic investment in the Sector, any MoU/ commitment from the interested investors to set-up units in the proposed Park etc.
- b. Provide financial projection taking into account projected revenue, budgetary allocation, estimated occupancy, operational expenses, interest expense (if any) and other relevant factors.
- c. Provide projected P&L, Balance Sheet, Cash Flow projection with detailed assumption and key ratio such as IRR, NPV, minimum occupancy for Break Even etc.

11. Regulatory Approvals:

Provide detail of all regulatory approvals and clearances required from State Govt. and Central Govt. with timelines, procedure and also whether the proposed Park and construction plan as per DPR is in compliance with the applicable regulations and standards.