

Letter of Expression of Interest

Dated: [Date]

To,

Materials Manager,
Haffkine Bio-Pharmaceutical Corp.Ltd.(HBPCL)
Acharya Donde Marg,Parel,Mumbai-400012
India

Attention: Mr.B G Dhekane

Email:mm@vaccinehaffkine.com / md@vaccinhaffkine.com / qa@vaccinehaffkine.com

Sub: Expression of Interest (EoI) for Appointment of technical consultants (projects)/firm for Haffkine Bio Pharmaceutical Corp Ltd.(HBPCL) future projects (Inactivated polio vaccine(IPV),pentavalent vaccine(DPT+HepB+Hib) ,tissue culture anti rabies vaccine(TCARV),upgradation & modernization of ani sera manufacturing facility at ATS Pimpri,Pune and Recombinant factor VIII & factor IX

Dear Sir,

With reference to your notice inviting submission of Expression of Interest dated [*date of advertisement*] published in [*name of publication*] (“*Notice for EoI*”), [we/ we (on behalf of the consortium comprising [*names of parties in consortium*] (“*Consortium*”))^{**}] hereby submit this Expression of Interest, with the requested information in Appendices 1 to 3 attached, [and, in addition, we have provided further information in Appendix 4 which we believe would be relevant for this EoI.^{!!}] for the captioned EoI . We submit this application under and in accordance with the terms of the Notice for EOI. [We have been duly authorised by the members of the Consortium to submit this EoI on behalf of the Consortium and to correspond with, and receive communication from, the Authority.^{##}]

[We/ We (on behalf of the Consortium)^{**}]

1. acknowledge that the HBPCL is acting (collectively the “**Authority**”) will be relying on the documents and information provided in this EoI and confirm that the documents and information provided with this EoI are true and accurate;
2. shall make available to the Authority any additional information it may consider necessary or require to supplement this EoI;
3. acknowledge that the Authority may cancel the process at any time without assigning any reason and that the Authority is not obliged to invite any applicant to bid for the EoI , without incurring any liability to the Applicant;
4. declare that [we/ any member of the Consortium^{**}], directly or through any of the

respective group companies, have not submitted an expression of interest in response to the Notice for EoI, nor are we a member of any other consortium that has submitted an expression of interest in response to the Notice for EoI;

5. hereby irrevocably waive, to the extent permitted by applicable law, any right or remedy which we may have at any stage at law or howsoever otherwise arising, to challenge or question any decision taken by the Authority in connection with the bidding process, including the entities to be invited to participate in the in the bidding process for the EoI;
6. agree with the terms stated in the Notice for EoI; and
7. acknowledge that this letter is not our offer in relation to the EoI.

All the members of the Consortium are bound by the terms of this EoI.

Yours faithfully,

[Signature, Name and Designation of the Authorized Signatory]

[!]: This is optional. Please delete if no further information (like literature about the applicant entity or members of the consortium) is being provided.]

[#: Please remove this if not applying as a

Consortium.] [**: Please delete as appropriate.]

Appendix-1

Details of Applicant/Members of Consortium

[Note:

1. *In case of a Consortium, please specify the following information in relation to each member of the Consortium].*
2. *Please provide the following information in relation also to the sole applicant's/each Consortium member's ultimate holding company.]*

1. Corporate details
 - (a) Name of the entity:
 - (b) Country of incorporation/registration:
 - (c) Date of incorporation/registration:
 - (d) Address of the corporate headquarters and its branch office(s), if any, in India:

2. Brief description of the core business activities of the applicant / [each member of the Consortium**]:

Name of Member of Consortium**	Core Business Activity**

3. Details of the authorised individual who will serve as the point of contact/ communication [on behalf of the Consortium**] with, and from, the Authority:
 - (a) Name:
 - (b) Designation:
 - (c) Address:
 - (d) Telephone Number: (office) [] (mobile) []
 - (e) E-Mail Address:
 - (f) Fax Number:

[**: Please delete as appropriate]

Appendix-2

1. Cash accruals details of the sole Applicant/ Members of the Consortium

Name of sole Applicant/ Members of Consortium	Net Cash Accruals (Rupees in million)			Average Net Cash Accruals during the last 3 years
	2016-17	2017-18	2018-19	

2. Details of net-worth of sole Applicant/ Members of Consortium

Name of sole Applicant/ Members of Consortium	Net-worth as on [] based on the last audited financial statements(Rupees in Million)

Instructions:

1. Copies of the audited financial statements (Balance Sheet, Profit & Loss Statement etc.) to support the above information relating to the Applicant/each member of the Consortium should be attached.
2. Net Cash Accruals shall mean Profit After Tax + Depreciation.
3. Net Worth shall mean (subscribed and paid-up share capital + free reserves) less (revaluation reserves + miscellaneous expenditure not written off).
4. In case the amounts required to be specified above are not in Indian Rupees, please convert other currencies into Indian Rupees using the most recent exchange rate available and specify such exchange rate in your submissions.

Appendix-3

Details of project works done or are being done by the Applicant/ Members of Consortium

1. Details of experience in Pharma/vaccine detailed project reports

Name of the Company	Role of Applicant/ Member of Consortium# (Engg/Technical)	Product (Name of Vaccine)	Scope of Work	Biotech Bulk API/ Injectable	Whether hired any external agency/partner (if yes then mention details)	Year in which work done	Current Status of Work

#: Such as direct consultation

***Work orders/Purchase order (without price) copies of previous projects to be attached**

Technical Consultant shall submit below details requirement:

1. Executive Summary
2. Objectives
3. Methodology
 - A. Study Design
 - B. Study Preparation
 - C. Scope of Study
 - D. Process of the study
 - i. Cost-benefit analysis
 - ii. Expected benefits of the study
 - iii. Results
 - a. Administration analysis
 - b. Technical and technological analysis
 - c. Vaccine technologies details
 - d. Economic and financial analysis
 - e. Criteria for feasibility study of vaccines (Technical as well as economical)
 - f. Model development for an economic feasibility study
 - iv. Demand supply mapping (current and next 5 years)
 - v. Details of potential markets(apart from India)
 - vi. Price of vaccine/dose in 2020 from various manufacturers
 - vii. Economic analysis of the vaccines
 - viii. Cost-benefit analysis of the vaccines
 - ix. Project Cost for the vaccines
 - a. Technology Cost for providing the viz:
 - i. Production Cell Lines
 - ii. Upstream process (common single protocol for all cell lines)
 - iii. Downstream process
 - iv. In-process control and quality control assays
 - v. Tentative Process Block Flow Diagram (USD,DSP)
 - vi. List of Process Equipments with capacities
 - vii. Transfer of the Biological Material,including :
 1. Research Cell Banks vials (10 for each L1

- serotype)
- 2. MOCK strain (1 vial)
- viii. One demonstration batch for one serotype at lab scale in Germany /principal company;including
 - 1. Upstream process (two cell lines expressing different L1 serotypes)
 - 2. Downstream process (1 serotype exemplarily)
 - 3. In-process control assays and quality control assays
- ix. 3 validation batches at site
- x. The cost should include any patents/royalty
- b. Engineering
 - i. Tentative area $\pm 30\%$
 - ii. Utility Area including warehouse
 - iii. Administration QA, QC Lab area
 - iv. Preliminary Single Line Layout based on the process flow diagram
 - v. Cost of the project for:
 - 1. Process Equipments
 - 2. HVAC & CRP
 - 3. Electrical, BMS, Automation
 - 4. Clean and black utilities
 - 5. Warehouse, clean room furnitures, miscellaneous
 - 6. Civil
- x. Discussion and conclusion
- xi. References

Apart from above information bidders should also provide following details:

1. Market analysis current and future demand of product
2. Financial analysis financial viability of project
3. Detailed project report, list of equipments, conceptual layouts, detailed civil construction, mechanical heating, ventilation air conditioning electrical, electronics, communication for cold rooms, boilers, WFI systems purified water system, effluent treatment plant.
4. Details of process flow, production steps, technology details, technical analysis
5. Quality control, details of various tests, instruments, equipments layout of Q.C.
6. WHO-GMP standards to be followed
7. Environmental clearance required
8. Animal House requirements
9. List of raw materials required
10. Technology Transfer
11. Methodology for commercial production
12. Total manpower requirements technical and non technical
13. Preparation of total detailed Bill of Quantity (BOQ)
14. Total cost of project/final budget with time line
15. All detailed engineering drawings
16. Time lines to complete project
17. Please fill up above table and details for the Applicant/ each member of Consortium.
18. In case the estimated turnover costs are not in Indian Rupees, please convert the amount into Indian Rupees using the most recent exchange rate available and specify such exchange rate in your submissions.
19. ATS Pimpri Anti Sera manufacturing unit: Refurbishment to meet cGMP norms as per WHO/Schedule M requirements
20. Cost should include if any Patent rights/royalty is there
21. Any other inputs, information as deemed fit for above projects execution.

Appointment of consultant/firm for Techno-commercial Feasibility Project Report for above mentioned 5 projects

Scope of Work

Markets: It covers estimated future sales revenue of the project based on estimated sales volumes and price for 3 to 5 years.

Raw Materials: It estimates the adequacy of the quality and quantity of the raw materials for the project, make an estimate of its cost.

Plant Siting, Location & Infrastructure: It assesses the existing infrastructure and actions required to develop the cGMP facility necessary to set up the new project.

Project Technical Concept: This is core deliverable of the project and covers plant capacity, equipment sizing, storages, plant auxiliaries/utilities, system engineering, electrical engineering, civil engineering, Control & Automation engineering, Quality Control & Assurance based on the project requirement.

Logistics: Inbound and outbound logistics and logistics planning.

Environment: Applicable Regulatory Framework and Environmental Impact of Project.

Implementation Planning: Time plan, Gant Chart, CPV/PERT

Human Resources: Requirement and cost.

Investment Cost: Fund requirement.

Operating Cost: It covers cost of raw material, utilities, overheads, etc.

Financial Appraisal: It covers project profitability, IRR, NPV, payback, etc.

Risks & Mitigation:- As applicable

Technology Transfer:

Terms & conditions, MOU, Agreement, CDA etc. as applicable

Various options for Tech Transfer:

1. Import & marketing of Finished Products(FPS) in India/South East Asia
2. Import of ready to Fill formulated bulk & make FPS
3. Import of Bulk for Formulation & Filling for FPS
4. In-house manufacturing of FPS (R&D, Pilot & Commercial Production Scale)

Methodology: Broad methodology of execution involves:

Data collection

Data analysis

Report and Project formulation

Benefits: To help HBPCCL to make an investment decision based on:

Technical feasibility of the project.

Financial viability of the project.

The risks associated with the project.

Actions required for risk mitigation.

Preparation of Project URS for manufacturing

This will be based on the following components based on the inputs from HBPCCL all the Department like Marketing, Production, Quality Control, Engineering and Quality Assurance.

- Local / Global approvals
- Annual production requirements of above five products from GOI, trade, UNICEF and Export.
- Capacity planning for current and future expansion
- Batch size consideration for bulk manufacturing and formulation
- Manpower planning for core areas like Manufacturing & Testing of bulk, formulation, filling and packing etc.
- Calendar operation for bulk preparation and formulation with shift and day wise.
- Schedule M and WHO GMP requirement for project site
- Master plan layout with location of above five products manufacturing facility
- Process flow diagram for preparation of plan layout
- Requirement of QC, IPQC, QA
- Requirement of animal testing facility

Stages of project with matrix of accountability by consultant and HBPCCL

1. Preparation of project cost estimate
2. Preparation of project schedule incorporating timelines of all civil and HVAC work.
3. Basic engineering
 - a. Conceptual layout preparation with block diagram
 - b. Risk impact analysis with QA, QC, Engg, Production and Consultant
4. Preparation of layout plan with schematic, man material movement, zoning etc.
5. Preparation of facility URS based on project URS with layout and site conditions to meet local and WHO regulatory requirements.
6. Preparation of room data books with details of equipment with loads, occupancy, room conditions
7. Preparation of gowning philosophy, Material air locks etc.

Detail Engineering

1. HVAC works

Heat load estimation.
HVAC Zoning, Sizing & Detailing of Chillers, AHU with/ without dehumidification system, Hot & Cold Piping & Insulation, Ducting etc.
HVAC airflow drawing for classified area systems.
HVAC control scheme & drawing with BMS.
AHU Sizing, location & Preparation duct layout.
Preparation of BOQ Document for all Classified & Non Classified Area. This Document includes all the drawing & technical specifications for major items.
Preparation of Tender Document for Complete HVAC System including erection, commissioning & Validation.
Preparation of URS & DQ for HVAC Equipment & System.

2. Process equipment

Preparation of detailed Equipment Load List including CIP/ SIP Skids.
Sizing of Process Equipment including Stand Alone Process Chilling Systems.
Preparation of URS with User-Assistance from consultants.

3. Other Utilities

Preparation of URS with capacities of all utilities.

4. Electrical

Prepare load list covering all buildings in the project including QC & Animal Testing and ancillary areas.

Preparation of single line diagram for HT & LT work including DG & UPS systems.

5. BMS & Access Control System:

Preparation of Conceptual Design for both systems.

Preparation of BMS Architecture.

Preparation BOQ & Tender Documents.

Preparation of Access Control Documents.

6. MECHANICAL:

Preparation of specs for Hot/ Cold Insulation Works.

Preparation BOQ & Tender Documents.

Floating Equipment, Obtaining Technical & Commercial Bids.

7. Plumbing & Sanitary Works:

Preparation of Drainage systems for Manufacturing Facility.

Preparation of specs for Pipes & Piping elements including that for Live & Non Live Areas going to Kill Tanks or ETP.

Preparation of Rain & Storm Water Drainage System for All Building.

Preparation BOQ & Tender Documents.

8. QC Laboratory & Experimental Animal House & Testing lab and QA Block:

Detailing of the Laboratory Equipment.

Preparation of URS for All Lab Equipment.

Preparation of Specification for QC Furniture.

Preparation of Specification of Sanitary Works for QC Lab to be covered in the BOQ of sanitary work for the project.

Detailing of QA including their Documentation storage areas, area for WHO/ other Auditors with respective works covered in each contract tender like HVAC, Electrical etc.

9. Other Works:

Architecture, Structure Design, Tendering & Civil Execution Works.

Statutory approvals/ permission etc.

Required minimum 3 years estimated project sales

Revenue based on estimated sales volume & cost

Project technical concept covers plan, capacity, equipment, sizing, storages, plant utility, HVAC, system engineering, electrical, civil engineering, control and automation engine (BMS), QC, QA

Inbound and outbound logistics and logistics planning

Applicable regulatory framework & environment impact of project & technology

Facility designing, Time plan. Gant chart

Manpower & cost

Operating cost: RM / PM Utilities, overheads etc.

Financial approval – project profitability, IRR, NPV, payback etc.

The risk associated with the project and actions required for risk investigation.

10. Work Completion period : 2 months (Tentatively)

Preparation of Final Budget submission to Management for Approval.

Scope of work for appointment of technical consultant for upgradation & modernisation of anti sera manufacturing unit at ATS Pimpri Pune.

Upgradation of ATS Facility as per WHO norms following area& Equipments needs to be undertaken for revamping /modification.

1. Stable Farm: Redesigning & modification of existing stable farm
2. Laboratory animal house: Redesigning & modification of existing Laboratory animal house
3. Snake Farm: Redesigning & modification of existing Snake Farm
4. Store Facility: Redesigning & modification of existing Store Facility
5. Bleeding Chamber: Redesigning & modification of existing Bleeding Chamber
6. Production Facility: Redesigning & modification of existing Production Facility
7. QC Facility; Redesigning & modification of existing QC Facility
8. Engineering & utility section Redesigning & modification of existing utility and Equipments
9. QA Section: Redesigning & modification of existing QA Department

In above mentioned facility /farms / departments /sections / areas needs few important changes and procurements of new equipments as per WHO Guidelines
And following are the scope of work

To Prepare Total cost of Project

1. Preparation of project schedule timelines of all civil and HVAC work.
2. Basic engineering
 - c. Conceptual layout preparation with block diagram
 - d. Risk impact analysis with QA, QC, Engg, Production ,veterinary and Consultant
3. Preparation of layout plan with schematic, man material movement, zoning etc.
4. Preparation of facility URS based on project URS with layout and site conditions to meet local and WHO regulatory requirements.
5. Preparation of room data books with details of equipment with loads, occupancy, room conditions
6. Preparation of gowning philosophy, Material air locks etc.

Detail Engineering

1. HVAC works

To Determine Heat load estimation.

HVAC Zoning, Sizing & Detailing of Chillers, AHU with/ without dehumidification system, Hot & Cold Piping & Insulation, Ducting etc.

HVAC airflow drawing for classified area systems.

HVAC control scheme & drawing with BMS.

AHU Sizing, location & Preparation duct layout.

Preparation of BOQ Document for all Classified & Non Classified Area. This Document includes all the drawing & technical specifications for major items.

Preparation of Tender Document for Complete HVAC System including erection, commissioning & Validation.

Preparation of URS & DQ for HVAC Equipment & System.

2. Process equipment

Preparation of detailed Equipment Load List including CIP/ SIP Skids.

Sizing of Process Equipment including Stand Alone Process Chilling Systems.
Preparation of URS with User-Assistance from consultants.

3. Other Utilities

Preparation of URS with capacities of all utilities.

4. Electrical:

Preparation of load list covering all buildings in the project including QC & Animal Testing and ancillary areas.

Preparation of single line diagram for HT & LT work including DG & UPS systems.

5. BMS & Access Control System:

Preparation of Conceptual Design for both systems.

Preparation of BMS Architecture.

Preparation BOQ & Tender Documents.

Preparation of Access Control Documents.

6. MECHANICAL:

Preparation of specs for Hot/ Cold Insulation Works.

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7. Plumbing & Sanitary Works:

Preparation of Drainage systems for Manufacturing Facility.

Preparation of specs for Pipes & Piping elements including that for Live & Non Live Areas going to Kill Tanks or ETP.

Preparation of Rain & Storm Water Drainage System for All Building.

Preparation BOQ & Tender Documents.

8. QC Laboratory & Experimental Animal House & Testing lab and QA Block:

Detailing of the Laboratory Equipment.

Preparation of URS for All Lab Equipment.

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Preparation of Specification of Sanitary Works for QC Lab to be covered in the BOQ of sanitary work for the project.

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Project technical concept covers plan, capacity, equipment, sizing, storages, plant utility, HVAC, system engineering, electrical, civil engineering, control and automation engine (BMS), QC, QA

Applicable regulatory framework & environment impact of project & technology

Facility designing, Time plan. Giant chart

Manpower & cost

Operating cost: RM / PM Utilities, overheads etc.

Financial approval – project profitability, IRR, NPV, payback etc.

The risk associated with the project and actions required for risk investigation.

Appendix-4

Customer testimonials to be attached as credentials:

Appendix-5

**Experts key profiles to be attached who are associated with your company/
consortium:**

Appendix-6

**[Note: This appendix may be used if the applicant or Consortium would like to provide
any additional information it considers relevant to the technical consultant appointment]**