

NOTICE INVITING EXPRESSION OF INTEREST (EOI)

ON BEHALF OF ITS SUBSIDIARY, HLL BIOTECH LIMITED (HBL)

FOR

SHORTLISTING VACCINE/ PHARMACEUTICAL MANUFACTURERS FOR USE OF HBL'S FACILITIES AT INTEGRATED VACCINES COMPLEX (IVC), CHENGALPATTU, ON "AS IS WHERE IS BASIS" FOR PRODUCTION OF COVID-19 /OTHER VACCINES.

EOI NO.HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21 DTD: 16/01/2021

BY

HLL LIFECARE LIMITED

[CIN U25193KL1966GOI002621]

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EOI Submission Details				
EOI NO.HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21				
DTD: 16/01/2021				
e- EOI reference no				
EOI publishing Date	:	16/01/2021 11:00 Hrs		
Pre EOI Meeting	:	22/01/2021 11:00 Hrs		
Last date for submission of EOI	:	29/01/2021 15:30 Hrs		
Date & time of opening of EOI	:	30/01/2021 16:00 Hrs		

1.0. INTRODUCTION

This Notice inviting Expression of Interest (EoI) seeks response from Vaccine/Pharmaceutical manufacturers for utilizing HBL's existing facilities at Integrated Vaccine Complex [IVC], Chengalpattu, Tamilnadu on "As is Where is Basis" for the production of COVID-19 vaccines or any other Vaccine. The facilities at IVC are offered on long-term lease/ contract manufacturing or any other mutually acceptable arrangement.

2.0. ABOUT HLL BIOTECH LTD

HLL Biotech Limited ("HBL") has been established under the Ministry of Health and Family Welfare, Government of India, as a 100% owned subsidiary of HLL Lifecare Limited (HLL), (A Government of India Enterprise) and a company incorporated under Companies Act 1956 with its registered office at HLL Bhavan, Poojappura, Thiruvanathapuram-695012, Kerala and having its Corporate Office at Integrated Vaccine Complex (IVC) Survey no.: 192&195, Thirumani Thirukazhukundram Taluk, Chengalpattu District, Tamil Nadu, India. HBL was formed in March 2012 for establishing Integrated Vaccines Complex (IVC) for manufacturing various vaccines required for Universal Immunization Programme (UIP) of Government of India. HBL is located in a campus of around 100 acres of government land, made available by CLTRI (Central Leprosy Teaching and Research Institute), Chengalpattu near Chennai. The different facilities/ units for bulk production, formulation, filling and support functions were established as per the CGMP requirements and some of the facilities are validated.

During the current COVID-19 pandemic, the development of COVID-19 vaccines is progressing in India and all over the world. HBL has been receiving communications from different companies in India for a partnership with HBL for COVID-19/Other vaccine production, formulation and filling activities.

Some parties have also visited the facility to check the feasibility to commence operations in the facility. Based on these enquiries, HLL received the direction to invite this EOI to shortlist potential party/parties for contract manufacturing/long term lease or any other mutually acceptable arrangement, for production of COVID-19 or other vaccines.

Vaccine production facilities available with HBL

HBL has established facilities for the production of following vaccines:

- Bulk production facilities for bacterial and viral vaccines.
- Formulation and filling facilities for liquid vaccines and lyophilized vaccines.
- Supporting facilities: QA, QC, warehouse, packaging, utility, animal house etc.

Some of the vaccine production facilities at IVC are commissioned and validated and some other facilities require commissioning and validation to make them ready for operation. The list of facilities at IVC and its current status is available at HBL website: www.hllbiotech.com and www.lifecarehll.com

3.0. INSTRUCTIONS TO PARTIES

- No Party shall submit more than 1 (one) EOI.
- Notwithstanding anything to the contrary contained in this document, the detailed terms specified in the Partnership agreement shall have overriding effect.
- HLL reserves the right not to proceed with the process at any time, without notice or liability, and to reject any EOI without assigning any reasons.
- The parties shall sign and seal all the pages of the EOI and attached documents while submitting the EOI.

4.0. ELIGIBILITY CRITERIA

- 1 The party shall be certified as a Vaccine OR Pharmaceutical manufacturer with at least 10 years own manufacturing experience.

 Copy of certificate to be submitted.
- 2 A brief write up about the applying company/entity to be submitted.
- 3 The party shall have at least one production facility in India or abroad, which is either certified by WHO/ US-FDA. Proof shall be submitted.
- 4 The party should have average annual turnover of INR.500 Cr or above during the last three Financial Years (2017-18, 2018-19, 2019-20). Audited balance sheet / CA certified turnover sheet should be submitted.
- 5 The party shall have a minimum net worth of Rs. 300 Cr as on 31.03.2020.
- 6 The party shall submit the tentative project operational plan with indicative time line for commercial production of vaccines from IVC.
- 7 Party shall be ready to make capital investment for making required facilities ready (not to be considered as equity) and working capital infusion for operationalizing the existing infrastructure/ invest for additional infrastructure, as per the requirement.
- 8 The party shall submit the details of the vaccines, which they intend to manufacture at HBL utilizing the facilities available.
- 9 Along with the EoI, the parties shall submit proof of the back-to-back arrangements with vaccine suppliers/manufacturers, technology providers in case they do not have own technology or knowhow for manufacture of Vaccine(s).
- 10 Corporate management approval for submission of Eol in response to this notification.

11 The party shall submit the willingness to operate the facility with existing manpower available with HBL and recruit/engage additional manpower as per the requirement.

5.0. CHECKLIST: DOCUMENTS TO BE SUBMITTED ALONG WITH SIGNED EOI

SI.	Name of document to be submitted	Document enclosed
No		(Yes/No)
1	Copy of company incorporation certificate	
2	Brief write about the company, products and	
	services.	
3	Production facility certification: WHO GMP certificate	
	or USFDA certificate.	
4	Audited balance sheet/CA certified turnover sheet	
	for last three financial years (2017-18,2018-19,2019-	
	2020)	
5	Company net worth statement certified by	
	Chartered Accountant	
6	Project operational plan document along with	
	tentative time line for commercial production of	
	vaccines from IVC.	
7	Letter from the party indicating the readiness for	
	capital investment in IVC for making certain required	
	facility ready for vaccine production and	
	commissioning & validation of such facilities as	
	required.	
8	Details of the vaccines proposed to be	
	manufacturered from IVC.	

9	Proof of arrangements made for supply of
	bulk/technology transfer for vaccines Or copy of MOU
	signed with different manufacturers for supply of bulk
	& technology transfer OR Agreement signed with
	different parties/manufacturers for supply of bulk &
	technology transfer for vaccines planned to be
	manufactured at IVC.
10	Letter indicating willingness to operate the facilities
	with available manpower and to add additional
	manpower as per the requirement.
11	Corporate management approval for submission of
	EOI.

6.0. PRE EOI MEETING

A Pre EOI meeting to discuss and clarify the details & requirements of EOI is scheduled on 22/01/2021 at corporate office, HLL Lifecare Limited, Trivandrum; 11:00 am to 12:00 pm through online platform. The online meeting link and details will be uploaded in CPP Portal as corrigendum.

7.0. EOI EVALUATION

- The shortlisting of parties shall be based on the evaluation of documents submitted as part of EOI.
- The shortlisted parties shall be provided the Request for Proposal (RFP)
 directly by HLL, which shall seek indicative financial terms for the
 partnership.
- Party/Parties for operationalizing IVC shall be finalized based on evaluation of RFP.

8.0. GENERAL

- i. Pre EOI meeting is scheduled for 22/01/2021
- ii. The deadline for submission of the EOI is 29/01/2021.
- iii. EOI should be valid for a period of 90 days from the date of opening of EOI response.
- iv. Conditional offers are liable for rejection.
- v. The Bidders should give clause by clause compliance of EOI with references to supporting documents; otherwise the offers are liable for rejection.
- vi. The Expression of Interest has been prepared in good faith and the parties shall sign & seal all pages of EOI & supporting documents. Parties are requested to do their own due diligence before submitting the EOI.
- vii. The parties are requested to keep the information and details strictly confidential. We are looking for your support and co-operation in getting fully responsive Expression of Interest.
- viii. HLL shall not be responsible for any expense incurred by Parties in connection with the preparation and delivery/submission of their EOI and other expenses.
- ix. HLL reserves the right to reject any or all the Expressions of Interest without assigning any reason thereof.
- x. HLL reserves the right to deal with the proposal in any manner without assigning any reasons for the same. The decision of HLL in this regard shall be final.

9.0. MODE OF SUBMISSION OF EXPRESSION OF INTEREST

Interested parties qualifying the eligibility criteria may submit the EOI and supporting documents in CPP portal, i.e., etenders.gov.in/eprocure/app.

The instructions regarding online EOI submission are given below:

 Party may download the EOI document from <u>www.etenders.gov.in/eprocure/app</u> or <u>www.lifecarehll.com</u>, or <u>www.hllbiotech.com</u>.

- 2. Party may have valid Digital Signature Certificate with encryption.
- 3. Parties are requested to read the help document on e-tender web site link before proceeding for EOI submission.
- 4. The prospective applicants have to register with the E-procurement system at https://etenders.gov.in/eprocure/app. On completion of the registration process, the applicants will be provided user ID and password. In order to submit the EOI electronically, applicants are required to have a valid Class 2/3 Digital Signature Certificate (signing and encryption/ decryption certificates).
- 5. Applicants are requested to register for issuance of User ID and Password well in advance in order to avoid last minute rush. The process normally takes 03 days' time.
- 6. Post receipt of User ID & Password, parties can log on for downloading & uploading EOI document.
- 7. Parties shall ensure that their EOI is complete in all respect (all supporting documents duly signed and sealed), are to be submitted online through e-procurement portal ONLY (as described above). No DEVIATION is acceptable.
- 8. A person signing (manually or digitally) the EOI or any documents forming part of the contract on behalf of another shall be deemed to warrantee that he has authority to bind such other persons and if, on enquiry, it appears that the persons so signing had no authority to do so, the purchaser may, without prejudice to other civil and criminal remedies.

The applicants may also contact toll free no. of the Central Public Procurement Portal for obtaining guidance to submit the EOI online.

9.0 Applicable Law and Jurisdiction:

This EoI, its meaning and interpretation, etc shall be governed by the Applicable Laws of India and shall be subject to the jurisdiction of the Courts at Madras.

For and on behalf of HLL Lifecare Ltd,

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