

# Global notice inviting Expression of Interest (EoI) for Ready to fill (RTF) bulk supply

**EOI No. HBL/IVC/RTF/17-18/001 dated 03.08.2017**

## Introduction

HLL Biotech Ltd, a 100% subsidiary of HLL Lifecare Limited, a Government of India Enterprise is setting up a centralized vaccine manufacturing facility, "Integrated Vaccine Complex" (IVC) at Chengalpattu, near Chennai, a "project of national importance" for strengthening the immunization program of Government of India.

The state of the art vaccine complex, a first of its kind in the public sector shall be the nodal center for research, development as well as manufacture of high quality, affordable, lifesaving vaccines to ensure the uninterrupted supply for the Universal Immunization Programme (UIP). This is aimed at reducing the demand supply gap in vaccines in the public sector. This would in turn ensure protection of the people of India from vaccine preventable diseases and hence lead to better health security of the country. The vaccines to be manufactured in the IVC in the initial phase are Pentavalent combination (DPT + Hepatitis B + Hib), BCG, Measles, Rubella, Measles + Rubella (MR), Hepatitis B, Human Rabies, Hib and Japanese Encephalitis vaccine. The annual capacity of IVC is expected to be around 585 million doses.

HLL Biotech Limited is on the lookout for potential business partners for the supply of ready to fill (RTF) bulk to manufacture the following vaccine products at HBL's integrated vaccine complex (IVC), Chengalpattu:

1. Measles stand-alone vaccine, Rubella stand-alone vaccine and Measles Rubella combined vaccine.
2. Rabies (human)
3. Hepatitis B
4. Japanese encephalitis (JE)
5. BCG
6. Tetanus Toxoid for conjugation to Hib polysaccharide.
7. Diphtheria Toxoid, Whole cell Pertussis and Tetanus Toxoid.

## Section I

### Invitation of Expression of Interest

HBL invites Expression of Interest (EOI) from potential partners having expertise in manufacturing of human vaccines for supply of ready to fill (RTF) bulk of the above mentioned vaccines at Integrated Vaccines Complex.

## Section II

### General Information

1. The deadline for submission of the EOI is 15.00 Hrs (IST) on 24<sup>th</sup> Aug 2017. EOI shall be submitted in a sealed envelope clearly super scribing on top of envelope, **“EXPRESSION OF INTEREST (EOI) FOR SUPPLY OF READY TO FILL BULK FOR MANUFACTURING VACCINES”**. Organizations are advised to carefully review the following and submit all relevant information along with their EOI.
2. HBL, may at its discretion, extend the last date for the submission of EOI, in which case all rights and obligations of HBL and the service providers subject to the previous deadline shall thereafter be subject to the deadline as extended.
3. HBL reserves the right to reject the EOI received after the last date for the submission.
4. The Tender Selection Committee reserves to right to cancel the N.I.EOI due to unavoidable circumstances and no claim in this respect will be entertained.

### Eligibility Criteria:

The bidder must be an existing vaccine manufacturer, who is manufacturing and supplying any of the vaccines mentioned in Section I.

In response to this EOI, the bidder is requested to submit the following documents, which will prove their expertise and experience in the vaccine development field as part of our evaluation:

1. Background about the bidder (Organization brochure) along with an overview on the products which they manufacture.
2. The Core Competencies of the Organization.
3. The bidder should have experience in India, and/or other key markets in marketing their vaccines.
4. The bidder must furnish the list of Organizations to which bulk supplied earlier.
5. The bidder shall submit the GMP certificate of their manufacturing facility.
6. The bidder shall submit the product registration certificate.
7. The bidder shall submit the marketing authorization certificate for the products that they are entitled to supply.
8. The bidder shall submit the details of their manufacturing capacity (installed and operational) for each product mentioned.
9. The bidder shall submit the details on the maximum quantity of each bulk that they can supply to HBL per annum.
10. Audited annual report of the bidder for the last three financial years.
11. While the EOI has been prepared in good faith, HBL does not make any representation or warranty, expressed or implied, or accept any responsibility or liability, whatsoever, in respect of any statement or omission herein, or the accuracy, completeness or reliability of information contained herein, and shall incur no liability under any law, statute, rules or regulations as to the accuracy, reliability or completeness of this request, even if any loss or damage is caused by any act or omission on its part.
12. Organizations are requested to keep the information and details strictly confidential. We are looking for your support and co-operation in getting a fully responsive EOI.

13. HLL Biotech Limited shall not be responsible for any expense incurred by Bidder in connection with the preparation and delivery of their EOI and other expenses
14. HBL reserves the right to reject any or all the EOI without assigning any reason thereof.
15. HBL reserves the right to deal with the proposal in any manner without assigning any reasons for the same. The decision of HBL in this regard shall be final.
16. Organizations shall also prepare Power Point presentations in respect of EOIs, submitted by them. HBL may invite Organizations, if required, to make Power Point presentations of their capability in the area
17. EOIs submitted in electronic formats like fax, emails etc. will not be accepted.
18. The EOI reaching HBL after the prescribed date and time shall be considered as late and will be rejected.
19. The commercial proposal will be invited from the parties once HBL short lists the parties based on the party's expertise and experience in bulk vaccine manufacturing, supply, technology transfer and product development of human vaccines. After evaluation / examination of the offers, HBL may at its sole discretion decide further course of action.
20. The bidder shall submit the details of annual turnover and net worth of the organization for the last three financial years.
21. The bidder should hold valid GMP (Good Manufacturing Practice)/WHO GMP Certificate issued by the Licensing authority. If the offered products are manufactured from more than one unit, all the units shall be GMP/WHO GMP certified.
22. The bidder should hold valid GLP (Good Laboratory Practice) Certificate issued by the licensing authority. If the offered products are manufactured from more than one unit, all the units shall be GLP certified.
23. The bidder shall not be convicted under the Drugs and Cosmetics Act and other laws administrated by the department and no prosecution actions shall be in progress or pending against the licensee and the license of the firm shall not be cancelled or suspended for noncompliance of provisions of Drugs and Cosmetics Act 1940 and the rules 1945.
24. Company which has been blacklisted by this Tender Inviting Authority in the past for any reasons or blacklisted/debarred by any State Government or Central Government Organization for the above reasons or for reason of furnishing forged/ fabricated/ false document should not participate in the tender during the period of blacklisting/debarring.
25. Where a product(s)/supplier is blacklisted in any other state or by a central Government agency for situations as detailed above occur after the submission /opening of the bid /award of contract, the product(s)/bidder will be liable for blacklisting/rejection/ termination/cancellation of contract/ purchase order etc. The product(s)/bidder will be liable for such action in the event of any conviction /initiation of prosecution action under the Drug and Cosmetics Act at any stage after submission/opening of bid.

**Validity of proposals:**

1. Proposal shall be valid for a period of 180 days from the last date of submission of proposals.
2. HBL retains the right that in exceptional circumstances at its own discretion, it may ask the applicants to extend the validity of their proposal for a specified period. The applicant not responding to the letter of extension of the validity period at that time shall not be further considered.

**Dates & Information:**

1. Interested bidders qualifying the above conditions may send their EOI with the necessary documents to the below mentioned address on or 15.00 Hrs (IST) on 24<sup>th</sup> Aug 2017.

**The Chief Executive Officer**  
**HLL Biotech Limited**  
**(A subsidiary of HLL Lifecare Limited)**  
**INTEGRATED VACCINE COMPLEX (IVC),**  
**SURVEY NO. 192 & 195,**  
**VILLAGE: THIRUMANI,**  
**TALUK: THIRUKAZHUKUNDRAM,**  
**CHENGALPATTU,**  
**KANCHIPURAM DISTRICT,**  
**PIN CODE - 603001, TAMILNADU**  
[ramanr@hllbiotech.com](mailto:ramanr@hllbiotech.com)

2. **Pre-Bid Meeting:**

HBL would host Service providers meeting at the venue and time mentioned below. The representatives of the interested organizations may attend the meeting at their own cost. The purpose of the meeting is to provide clarifications, if any to the service providers regarding EOI.

**Date: 10.08.2017**

**Venue: HLL Biotech Limited,**  
**INTEGRATED VACCINE COMPLEX (IVC),**  
**SURVEY NO. 192 & 195, VILLAGE: THIRUMANI,**  
**TALUK: THIRUKAZHUKUNDRAM, CHENGALPATTU. PIN – 603001, T.N**