Global notice inviting Expression of Interest (EoI) for Supply of Bulk Antigen, Ready to fill (RTF) bulk, seed, seed & technology.

EOI No. HBL/IVC/Re_RTF/18-19/001 dated 05.04.2018

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 Bulk antigen, Ready to fill (RTF) bulk, seed, seed & technology of the below mentioned vaccines at Integrated Vaccine Complex.

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 and 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 Bulk antigen, Ready to fill (RTF) bulk, seed, seed & technology to manufacture

the following vaccine products at HBL's Integrated Vaccine Complex (IVC), Chengalpattu:

1. Measles stand-alone bulk antigen, Rubella stand-alone bulk antigen and/or Measles Rubella combined RTF bulk.
2. Measles – Seed / Seed & Technology, Rubella –Seed / Seed & Technology.
3. Rabies (human) – Bulk Antigen / RTF Bulk / Virus Seed.
4. Hepatitis B - Bulk antigen / RTF Bulk.
5. Japanese encephalitis (JE) - Bulk Antigen / RTF Bulk.
6. Tetanus Toxoid bulk antigen for conjugation to Hib polysaccharide.
7. Purified Diphtheria Toxoid bulk antigen, Whole cell Pertussis individual/pooled bulk antigen and Purified Tetanus Toxoid bulk antigen.

Section II

General Information

1. The deadline for submission of the EOI is 15.00 Hrs (IST) on 04th May 2018. EOI shall be submitted in a sealed envelope clearly super scribing on top of envelope, **"EXPRESSION OF INTEREST (EOI) FOR SUPPLY OF BULK ANTIGEN, READY TO FILL (RTF) BULK, SEED, SEED & TECHNOLOGY 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 EOI evaluation committee reserves to right to cancel the N.I.EOI due to unavoidable circumstances and no claim in this respect will be entertained.
5. 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, statue, 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.

6. 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.
7. 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.
8. HBL reserves the right to reject any or all the EOI without assigning any reason thereof.
9. 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.
10. 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.
11. EOIs submitted in electronic formats like fax, emails etc. will not be accepted.
12. The EOI reaching HBL after the prescribed date and time shall be considered as late and may be rejected.
13. 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.

- **Eligibility Criteria for Supply of Bulk antigen and RTF bulk: -**

The bidder shall be an existing vaccine manufacturer, who is manufacturing and supplying any of the vaccines or an authorized agent /distributor appointed by the manufacturer to represent in the EOI, 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 who is a vaccine manufacturer should have previous experience either in India, and/or other key markets across the globe in marketing their vaccines mentioned in Section-I.
4. The bidder who is an authorized agent/distributor of the vaccine manufacturer should have previous experience in importing the bulk to India as per the regulatory requirement of national regulatory authority in India.
5. If the bidder is the agent/distributor of the manufacturer, they should submit the authorization letter from the manufacturer authorizing them to participate in the tender invited by HBL and also to supply the RTF/bulk to HBL on behalf of the manufacturer.
6. The bidder must furnish the list of Organizations to which Bulk antigen / RTF bulk if they have supplied earlier. Bidder shall submit corresponding work orders or purchase orders or any agreements as documentary proof. If the bidder has no prior experience in supplying Bulk antigen / RTF bulk, then HBL reserves the right to consider their bids for evaluation based on their technical competencies/supply potential. HBL may also visit their facility as a part of evaluation and the party may also be invited to HBL office for making a presentation to prove their capability in supplying the bulk to HBL.

7. The bidder shall submit the GMP certificate of their manufacturing facility.
8. The bidder shall submit the product registration certificate/ marketing authorization certificate for their finished products as mentioned in Section I.
9. The bidder shall submit the details of their manufacturing capacity (installed and operational) for each finished product.
10. The bidder shall submit the details on the maximum quantity of each product that they can supply to HBL per annum.
11. The bidder shall submit the shelf life/hold time of the product (bulk antigen, RTF bulk and finished products) along with its relevant documents for which the bidder has participated.
12. Audited annual report, annual turnover and net worth of the bidder shall be provided for a minimum of last one financial year and / or maximum of last three financial years (ending on 31st March'17).
13. Net worth of the bidder should be positive for the last financial year (ending on 31st March'17).
14. The bidder shall not be convicted under the Drugs and Cosmetics Act/NRA 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.
15. 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.
16. Where the 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.

Note: A self-declaration letter on their company's letter head, signed by the competent authority for point no. 14 to 16 shall be furnished.

- **Eligibility Criteria for Supply of Seed and / or Seed & Technology: -**

The bidder can be an existing vaccine manufacturer, who is manufacturing and supplying any of the vaccines mentioned in Section I and or an authorized agent /distributor appointed by the manufacturer /or and an Institute or a research agency capable of offering seed and/or seed and technology.

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 must furnish the list of Organizations to which seed and/or seed and technology if they have supplied earlier. Bidder shall submit corresponding work orders or purchase orders or any agreements/MOU as documentary proof. If the bidder has no prior experience in supplying seed and/or seed and technology, then HBL reserves the right to consider their bids for evaluation based on their technical competencies/supply potential. HBL may also visit their facility as a part of evaluation. The party may also be invited by HBL for making a presentation to prove the capability/eligibility in supplying the seed & seed and technology to HBL for the vaccine.
4. The bidder shall submit the GMP/GLP or other certificates of their manufacturing/research facility.

5. If the bidder has commercialized the product using this seed and technology, then the following shall be furnished.
    - The marketing authorization certificate for the products that they are entitled to supply.
    - The details of their manufacturing capacity (installed and operational) for each product mentioned.
    - The details of the shelf life of the product.
6. Audited annual report, annual turnover and net worth of the bidder shall be provided for a minimum of last one financial year and / or maximum of last three financial years (ending on 31st March'17).
7. Net worth of the bidder should be positive for the last financial year (ending on 31st March'17).
8. The bidder shall not be convicted under the Drugs and Cosmetics Act/NRA 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.
9. 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.
10. 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.

Note: A self-declaration letter on their company's letter head, signed by the competent authority for point no. 8 to 10 shall be furnished.

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 04th May 2018.

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
ceo@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 and Time: 13.04.2018 at 11:00 AM

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

Note: Prospective bidders who are interested to attend the Pre-Bid meeting shall intimate HBL by sending an email to ceo@hllbiotech.com