



HLL LIFECARE LIMITED
(A Government of India Enterprise)
KANAGALA

BELAGAVI DIST. PIN – 591 225
KARNATAKA STATE
PH.NO: 08333-279239, 279244, 279207
FAX: 08333-279245
Website: www.lifecarehll.com

EXPRESSION OF INTEREST
No. HLL: BG: SOURCE: EOI: CM: LL: 01: 2015-16
DT.07.01.2016

TENDER DOCUMENT

FOR

**“EMPANELMENT OF MANUFACTURERS FOR MANUFACTURE &
SUPPLY OF INJECTABLE CONTRACEPTIVES ON LEASE/ CONTRACT
MANUFACTURING / UNDER LOAN LICENCE”**

Last date and time for Receipt of Technical Bid : **28.01.2016 up to 11:00 Hrs.**

Date and time of opening of Technical Bid : **29.01.2016 at 11:00 Hrs.**

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Expression of Interest

HLL Lifecare Limited (Formerly Hindustan Latex Limited) (HLL) is a 'Mini Ratna' PSU under the Ministry of Health & Family Welfare, Govt. of India involved in the promotion of Pharmaceutical Products through its newly formed Women Healthcare Division. HLL invites Expression of Interest from interested Manufacturers **TO MANUFACTURE & SUPPLY OF VARIOUS INJECTABLE CONTRACEPTIVES ON LEASE/ CONTRACT MANUFACTURING / UNDER LOAN LICENCE**. Its contents etc are given in this Bid document.

The scope of work under the present Expression of Interest covers the following:

- 1. Provide the existing established facility for manufacture of Injectable Contraceptives.**
- 2. Manufacture & Supply of various Injectable Contraceptives on Lease/Contract Manufacturing / Under Loan License.**
- 3. Ensure strict compliance to all statutory regulations with furnishing of a "Certificate of Analysis" confirming to Drugs & Cosmetics Act prevailing in India for each batch of all products manufactured from the facility.**
- 4. Follow the CGMP practices throughout the process.**
- 5. Ensuring Production of quality products at all stages and at all time.**
- 6. Maintenance of online Batch manufacturing record as per the requirement of D & C ACT and the rules there of.**

The details of item, item specifications and terms & conditions etc. are given in Tender documents. The same can be had from our Office on any working day between 11:00 AM to 3:30 PM by paying ₹ 5000/- by Cash / DD / Banker's Cheque (inclusive of ST) drawn in favour of HLL Lifecare Limited, payable at State Bank of India, NIPANI - 591 237. Further, Tender documents can also be downloaded from our website **www.lifecarehll.com**. OR Govt. Procurement Portal **eprocure.gov.in** However cost of **Tender documents i.e. ₹ 5000 /- by D.D/Banker's Cheque shall be given along with the Technical Bid.**



Last date for Receipt of Technical Bid	28.01.2016 (11:00 Hrs.)
Opening of Technical Bids	29.01.2016 (11:00 Hrs.)
*EMD amount to be deposited	₹ 1.00 Lakh

We request you to submit your sealed Technical bid for the Empanelment of Manufacturers to manufacture & supply of Injectable Contraceptives on Lease/Contract Manufacturing/Under Loan License.

In case you need any further information, please feel free to contact the undersigned on E-mail: natesh@lifecarehl.com. Ph. No: 08333-279543, cell 09945618811. Mr. Natesh K.

JOINT GENERAL MANAGER (SOURCING)



BID DATA SHEET

Address for Submission of Bids	JOINT GENERAL MANAGER (SOURCING) HLL Lifecare Limited (A Govt. of India Enterprise) Kanagala – 591 225 Belagavi Dist. Karnataka Tel: 08333 – 279239 / 44
Bid validity	90 days from the date of bid opening.
No. Of copies	No. Of copies: 1 original
Dead line for submission of Technical Bid	Date: 28.01.2016, Time: 11:00 Hrs.
Date of opening of Technical Bid	Date: 29.01.2016, Time: 11:00 Hrs.

BACKGROUND NOTE

1. Company Background

HLL Lifecare Limited (formerly Hindustan Latex Limited) (HLL) is a Mini Ratna (Category-1 PSE) company under the Ministry of Health and Family Welfare. Our Corporate head office is at Thiruvananthapuram, Kerala. We have seven production units – two in Thiruvananthapuram, one each at Kakkanad, Irapuram in Kerala and one each at Kanagala, Belagavi, Karnataka & Indore M.P., and Manesar, Haryana. Procurement & Consultancy Office at Noida, Manufacturing facility at CSEZ and Marketing Offices around the Country. We have Five subsidiaries viz., HLL Biotech Ltd., Goa Antibiotics Ltd., HLL Infra Tech Services Ltd., Lifespring Hospitals (P) Ltd., and HLL Management Academy.

HLL has developed an impressive production infrastructure for a range of Contraceptives and Health Care Products. We are also planning to venture into new and challenging frontiers in the area of Health Care such as Vaccines, R&D, Hospitals and Pharmaceuticals. The total employees strength of HLL is around 5000.



PROPOSED PRODCUT LIST.

1.

Sl. No.	Product Name
1.	Progestin only: 150 mg depot medroxyprogesterone acetate (DMPA)
2.	Progestin only: 200 mg norethindrone (norethisterone) enanthate (NET EN)
3.	Progestin +Estrogen: 25 mg DMPA +5 mg estradiol cypionate
4.	Progestin +Estrogen: 50 mg NET EN +5 mg estradiol valerate
5.	Progestin +Estrogen: 150 mg Dihydroxy Progesterone Acetophenide + 10 mg estradiol enanthate
6.	Half-dose: 75 mg Dihydroxy Progesterone Acetophenide + 5 mg estradiol enanthate
7	Progestin + Estrogen: 250 mg 17 μ -hydroxy- progesterone Caproate + 5 mg estradiol valerate



ELIGIBILITY CRITERIA FOR BIDDERS

- a) The manufacturer should have valid WHO GMP/GMP certificate for manufacturing facility for manufacture of various injections as mentioned in the Tender Document. Copy of certificate shall be enclosed with Technical Bid.
- b) The manufacturer should have a valid manufacturing license on the date of Bid opening. Copy of manufacturing license along with list of products must be provided.
- c) The manufacturer should have average annual Turnover of ₹ 10.00 Crores (Ten Crores) during any one of the last three financial years i.e. 2012-13, 2013-14 & 2014-15. Annual Report / Certificate from Chartered Accountant shall be enclosed.
- d) Annual production capacity Certificate for Injectable Contraceptives should be submitted which is counter signed by Chartered accountant or any other statutory body.
- e) The tenderer should have No-Conviction Certificate for last 1 year (Self attested copy should be enclosed).
- f) Copy of Site Master File must be enclosed.
- g) A Demand Draft/Banker's Cheque for ₹ 1,00,000/- towards Earnest Money Deposit, drawn in favour of "HLL Lifecare Ltd." and payable at SBI, Nipani – 591 237 shall be enclosed.
- h) A Demand Draft / Banker's Cheque for ₹ 5,000/- towards cost of Tender Form , drawn in favour of "HLL Lifecare Ltd." and payable at SBI, Nipani – 591 237 shall be enclosed.
- i) A self-declaration to enter into an agreement as stipulated in the tender document in case of contract manufacturing /under Under Loan License manufacturing/ leasing of facility within 10 days from the date of issue of order needs to be enclosed with Technical Bid,



SCOPE OF WORK

1. General Scope

- 1. Provide the existing established facility for manufacture of Injectable Contraceptives.**
- 2. Manufacture & Supply of various Injectable Contraceptives on Lease/Contract Manufacturing / Under Loan License.**
- 3. Ensure strict compliance to all statutory regulations with furnishing of a “Certificate of Analysis” confirming to Drugs & Cosmetics Act prevailing in India for each batch of all products manufactured from the facility.**
- 4. Follow the CGMP practices throughout the process.**
- 5. Ensuring Production of quality products at all stages and at all time.**
- 6. Maintenance of online Batch manufacturing record as per the requirement of D & C ACT and the rules there of.**

GENERAL INSTRUCTIONS TO BIDDERS

1. Ethical Standard

- 1.1 Bidders are expected to observe the highest standard of ethics during the procurement and execution of this Contract. In pursuit of this policy, HLL will reject a proposal for award if it determines that the Bidder being considered for award has engaged in corrupt or fraudulent practices in competing for the Contract

For the purposes of this provision, the terms set forth below are defined as follows:

- (i) Corrupt practice: means the offering, giving, receiving, or soliciting of any thing of value to influence the action in the procurement process or in Contract execution; and
- (ii) Fraudulent practice: means a misrepresentation of facts in order to influence procurement process including collusive practices designed to establish bid prices at artificial, non-competitive levels to deprive HLL of the benefits of competition;



2. Cost of Bidding

The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Purchaser will in no case be responsible or liable for those costs.

3. Clarification of Bidding Documents

- a) A prospective Bidder requiring any clarification of the Bidding Documents may notify the Purchaser in writing, or by fax at the purchasers mailing address indicated in the Invitation for Bids. The Purchaser will respond in writing to any request for clarification of Bidding Documents, which it receives not later than 5 days prior to the deadline for submission of Bids prescribed by the Purchaser.
- b) During the bid evaluation, the Purchaser may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the price or substance of the bid shall be sought, offered, or permitted.

4. Amendment of bidding documents

- a) At any time prior to the deadline for submission of bids, the Purchaser may, for any reason, modify the Bidding Documents by amendment in company website only.
- b) The amendment will be notified in writing or fax or telegram or e-mail to all prospective Bidders, which have received the Bidding Documents and will be binding on them.

Preparation of Bids

5. Language of Bid

All correspondence and documents related to the bid shall be in English.

6. Documents Accompanying the Bid

The Response to mandatory requirements shall consist of:

- a. A forwarding letter indicating the submission of sealed Technical Bid. An authorized person holding the Power of Attorney should sign the letter.
- b. Power of Attorney in original and/or duly notarized.
- c. Signed copy of Tender Document (all pages to be signed & stamped)



- d. Organization structure of the Bidder & escalation mechanism.
 - e. Copy of the Manufacturing License from competent authority.
 - f. Copies of executed any orders, if available.
7. For all the parts of the Bid, the Bidder shall prepare one original bid as per Bid Data Sheet (BDS). The Bid consisting of the complete set of documents shall be signed by the Bidder or a person duly authorized to bind the Bidder to the Contract. All pages of the bid shall be numbered except for un-amended printed literature, which shall be initialed by the person signing the bid.
 8. The bid shall contain no interlineations, erasures, or overwriting, except to correct errors made by the Bidder, in which case the person or persons signing the bid shall initial such corrections.

9. Period of Validity.

Empanelment shall remain valid up to 3 years from the date of signing the agreement; further renewal shall be made upon mutual agreed terms.

Submission of Bids

10. Sealing and Marking of Bids

- i) The Bidder shall prepare and seal in an **envelope** with requisite documents super scribing the envelope as **EXPRESSION OF INTEREST NO. HLL: BG: SOURCE: EOI:CM:LL:01:1015-16 DT. 07.01.2016 -**

- **Bid for Empanelment of Manufacturer to Manufacture & Supply of various INJECTABLE CONTRACEPTIVES ON LEASE/CONTRACT MANUFACTURING/ UNDER LOAN LICENSE.**

The envelope shall be addressed to HLL at the address given in the bid data sheet and

- ii) Bear the Contract name, the Invitation for Bids title and number, and the statement **DO NOT OPEN BEFORE 28.01.2016** (Mention the date of opening of the bid as given in the tender documents).
- iii) EMD & Bid Document fee shall be sealed in a separate envelope.
- iv) If the outer envelope is not sealed and marked as required HLL will assume no responsibility for the bids misplacement or premature opening.



11. Deadline for Submission of Bids

Bids must be received by HLL at the address specified in the bid not later than the time and date stated in the bid. HLL may, at its discretion, extend this deadline for submission of bids in which case all rights and obligations of HLL and Bidder thereafter be subject to the deadline as extended.

12. Late Bids

Any bid received by HLL after the bid submission deadline prescribed by HLL in the bid, will be rejected and returned unopened to the Bidder.

13. Modification and Withdrawal of Bids

Bids once submitted should not be modified. However in exceptional cases where modification is inevitable, the following procedure for the same should be adopted.

- 14.1 Modification will be permitted only if a written notice of the same is received by HLL prior to the deadline prescribed for bid submission.
- 14.2 The Bidder's modifications shall be prepared, sealed, marked, and dispatched as follows
 - (a) The Bidders shall provide copy of any modification(s) to its bid, clearly identified as such, marked BID MODIFICATIONS ORIGINAL The envelope shall be sealed in which shall be duly marked BID.
- 14.3 A Bidder wishing to withdraw its bid shall notify HLL in writing prior to the deadline prescribed for bid submission. The withdrawal notice shall be addressed to HLL at the address named in the bid data sheet and bear the Contract name, and the words BID WITHDRAWAL NOTICE. Bid withdrawal notices received after the bid submission deadline will be ignored and the submitted bid will be deemed to be a validly submitted bid.
- 14.4 No bid may be withdrawn in the interval between the bid submission deadline and the expiration of the bid validity period specified.
- 14.5 In the event of the date specified for bid receipt and opening being declared as a closed holiday for purchaser's office, the due date for submission of bids and opening of bids will be the following working day at the appointed times.
15. The purchaser may, at its discretion, extend this deadline for submission of bids by amending the Bid Documents or any other reasons, in which case all rights and obligations of the Purchaser and Bidder previously subject to the deadline will thereafter be subject to the deadline as extended, in our website.



Purchaser will not be held responsible for the postal delay, if any, in the delivery of the bidding document or the non-receipt of the same. Bids sent by Telex/Fax/Telegraph will not be accepted.

The company reserves the right to club or split the items of works, change the qualifying criteria at their discretion and to reject the bid or cancel the tender without assigning any reason thereof.

Bid Opening and Evaluation

16. Opening of Bids by HLL

Bids received before the dead line of the submission of the bid will be opened on the date and time of opening mentioned in the Bid Data Sheet (BDS).

Bidders wishing to be present at the time of such opening may send their duly authorized representative.

17. Preliminary Examination of Bids

17.1 HLL will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required securities have been furnished, whether the documents have been properly signed, and whether the bids are generally in order.

17.2 HLL may waive any minor nonconformity, or irregularity in a bid that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.

18. Clarifications on Bids

During the bid evaluation, HLL may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the price or substance of the bid shall be sought, offered, or permitted.

19. Contacting HLL

19.1 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact HLL on any matter related to the bid, he shall do so in writing.

19.2 If a Bidder tries to influence HLL directly or otherwise, interfere in the bid evaluation process and the Contract award decision, his bid will be rejected.



20. HLL's Right to Accept or reject any or all Bids

20.1 HLL reserves the right to accept or reject any bid or to annul the bidding process and reject all bids at any time prior to Contract award, without assigning any reason thereof.

20.2 HLL reserves the right to inspect the manufacturing premises, if so Warranted before empanelment and any time during the contract period

21. Notification of Award

Prior to the expiration of the period of bid validity, HLL will notify the successful Bidder in writing that its bid has been accepted.

22. Signing of Contract

22.1 At the same time as HLL notifies the successful Bidder that its bid has been accepted, HLL will send the Bidder the Contract Form provided in the Bidding Documents, incorporating all agreements between the parties.

22.2 Not more than ten (10) days following receipt of the Contract Form, the successful Bidder shall prepare the contract agreement on a Non Judicial stamp paper of ₹ 100/-, sign, date and return it to HLL.

In case, the successful bidder does not do so, HLL in its discretion may cancel the bid of the successful bidder and may accept the bid of the next higher bidder and the successful bidder also be liable to pay damages to HLL.



SPECIFIC TERMS & CONDITIONS OF CONTRACTS

1. The manufacturer shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or person what so ever.
2. The manufacturer must submit Batch wise Test Analysis report of the INJECTABLE CONTRACEPTIVES from NABL certified laboratories only in original along with each consignment.
3. The manufacturer shall submit batch wise samples of INJECTABLE CONTRACEPTIVES supplied to the undersigned before the commencement of supply.
4. The INJECTABLE CONTRACEPTIVES shall be supplied in the package specified and the package shall carry the logograms specified.
5. No advance payment towards costs of INJECTABLE CONTRACEPTIVES etc. shall be made to the supplier. The payment against part supply will not be entertained.
6. On completion of supplies of ordered quantities bills/Invoices should be raised in triplicate in the name of HLL Lifecare Limited.
7. If any time a particular INJECTABLE CONTRACEPTIVES is found damaged or the packaging has deteriorated or the test reports has failed then the supplier has to replace the whole quantity of item at his own cost within 30 days.



CONDITIONS OF THE CONTRACT

1. Settlement of Disputes

1.1 Arbitration shall not be a means of settlement of any dispute or claim arising out of the contract relating to the work. Any disputes or difference arising between the parties with respect to the performance of any part of this agreement or any thing connected therewith, etc shall as far as possible be mutually settled by the process of dialog and negotiation.

1.2 Conciliation/Arbitration

Any disputes or differences or questions or claims arising under or relating to a concerning or touching this agreement shall be referred for arbitration in accordance with the provisions of the Arbitration and Conciliation Act 1996.

The arbitration proceedings shall be held at Thiruvananthapuram. The award passed by the arbitrator shall be final and binding on the parties hereto.

The conduct of such arbitration shall be in English

1.3 No suspension of work

The obligations of HLL and the bidder shall not be altered by reasons of conciliation/arbitration being conducted during the progress of works. Neither party shall be entitled to suspend the work on account of conciliation/arbitration and payments to the bidder shall continue to be made in terms of the contract.

1.4 Award to be binding on all parties

The award of the Sole Arbitrator, unless challenged in court of law, shall be binding on all parties.

1.5 Jurisdiction of Courts

The Courts at Thiruvananthapuram alone shall have jurisdiction in respect of settlement of any matter arising out or in connection with the contract.

2. Time for Commencement and Acceptance

The Bidder shall commence work within one week from date of issue of Letter of Acceptance / as per HLL requirement.



3. Bidders Responsibilities

- 3.1 The Bidder shall be responsible for timely provision of all resources, information, and decision making under its control that are necessary to reach a mutually Agreed and Finalized Plan within a period of two (2) weeks from the date of issue of Letter of Acceptance.
- 3.2 The bidder shall acquire in the name of HLL, all permits, approvals, and/or licenses from all local, state, or national government authorities or public service undertakings that are necessary for the performance of the Contract.
- 3.3 The bidder shall comply with all laws in force in India. The laws will include all national, provincial, municipal, or other laws that affect the performance of the Contract and are binding upon the bidder. The Bidders shall indemnify and hold harmless HLL from and against any and all liabilities, damages, claims, fines, penalties, and expenses of whatever nature arising or resulting from the violation of such laws by the bidder or its personnel. Except that caused by HLL.
- 3.4 The bidder shall provide and employ only such personnel who are skilled and experienced in their respective callings and supervisory staff who are competent to adequately supervise the work at hand.

In particular, the key personnel namely the Project Leader, Quality Assurance personnel any Specialist/Analysts required as appropriate, need to have sufficient experience in terms of relevance and number of years required for the contract.
- 3.5 If for any reason beyond the control of the bidder, there arises a need to replace any personnel, the Bidders shall provide a replacement person of equivalent or better qualification and experience, subject to the written approval of HLL.
- 3.6 The bidder/bidders representatives in HLL shall bind to obey the rules and regulations of HLL.

4. Terms of Payment

WILL BE DECIDED AT THE TIME OF SIGNING OF MOU/AGREEMENT.

5. Delivery Schedule

THE QUANTITY TO BE DELIVERED WILL BE INTIMATED AS PER THE SCHEDULE GIVEN FROM TIME TO TIME – F.O.R: Various consignees of various States.



6. Taxes and Duties

The Bidder shall bear and pay all taxes, duties, levies, and charges assessed on the bidder by all municipal, state, or national government authorities, in connection with the Goods and Services supplied under the Contract. Income Tax and Other Taxes as applicable at the time of execution of job or any other government-imposed liabilities would be deducted from each bill submitted by the bidder.

7. Intellectual Property

All rights including the Intellectual Property Rights subsisting in any material including any tools, utilities or methodologies belonging to the Bidders and used to perform the obligations under this Agreement shall remain vested in the Bidders (the Bidders Properties) and any additional or new inventions made in the course of performance of services shall belong to HLL.

8. Confidential Information

HLL and the Bidder (the Receiving Party) shall each keep confidential and shall not, without the written consent of the other party to this Contract (the Disclosing Party), divulge to any third party any documents, data, or other information of a confidential nature (Confidential Information), that has been marked Confidential (Confidential Information)

9. Force Majeure

Force Majeure shall mean any event beyond the reasonable control of HLL or of the Bidders, as the case may be, and which is unavoidable notwithstanding the reasonable care of the party affected and shall include, without limitation, the following

- (a) War, hostilities, or warlike operations (whether a state of war be declared or not), invasion, act of foreign enemy, and civil war;
- (b) Rebellion, revolution, insurrection, mutiny, usurpation of civil or military government, conspiracy, riot, civil commotion, and terrorist acts;
- (c) Strike, sabotage, lockout, embargo, import restriction, industrial dispute, epidemics, quarantine, and plague;



- (d) Earthquake, landslide, volcanic activity, fire, flood or inundation, tidal wave, typhoon or cyclone, hurricane, storm, lightning, or other inclement weather condition, nuclear and pressure waves, or other natural or physical disaster immediately effecting project implementation;

If either party is prevented, hindered, or delayed from or in performing any of its obligations under the Contract by an event of Force Majeure, then it shall notify the other in writing of the occurrence of such event and the circumstances of the event of Force Majeure within fourteen (14) days after the occurrence of such event.

Change in Contract Elements

10. Termination

HLL may at any time terminate the Contract for any reason by giving the Bidders a thirty days (30) notice of termination

11. Termination for bidders Default

- (a) If the Bidder assigns or transfers the Contract or any right or interest therein in violation of the provision of Clause 13(Assignment); or
- (b) If the bidder, in the judgment of HLL, has engaged in corrupt or fraudulent practices in competing for or in executing the Contract, including but not limited to willful misrepresentation of facts concerning ownership of Intellectual Property Rights in, or Proper authorization and/or licenses from the owner to offer, the hardware, software, or materials provided under this Contract.

12. Assignment

The bidder shall not, without the express prior written consent of HLL, assign to any third party the Contract or any part thereof, or any right, benefit, obligation, or interest therein or there under.

**FORMAT-1****SELF-DECLARATION**

To,
Joint General Manager (Sourcing)
HLL Lifecare Limited
Kanagala - 591225
Belagavi Dist, Karnataka.

Dear Sir,

This is to certify that our Company has not been Black Listed either by State Government or Government of India in connection with Manufacturing or Sourcing, Packaging & Distribution of Injectable Contraceptives & other related medical devices.

Date:
Place:

Signature:

Name:
Designation:

Common Seal: