



AMENDMENT NO.1 Dated 23.05.2025

Ref IFB No: HLL/PSD/RBD/2025-26/TENDER/21 Dt: 21.05.2025

E-Tender ID: 2025_HLL_236010_1

The following amendment has been incorporated in the above mentioned tender for Supply of Pharmaceutical Products for Onward Supplies to Foreign Country.

For

1. Section 1 Clause No.03;

TECHNICAL SPECIFICATION

All Pharmaceutical products should have relevant & valid WHO GMP certificate and COPP (Certificate of Pharmaceutical Product).

Should submit relevant document for all the quoted items complying with BP/USP/IP standards specified in Annexure 4 technical specifications.

2. Section 2

Clause no.01 Eligible bidders

Bidders are requested to submit the Tender processing fee and EMD online on or before the due date as mentioned in the NIT. The bidders who failed to submit the tender fee and EMD before the submission deadline will be considered as technically non responsive.

A Bidder should have following eligibility criteria as of the date of bid submission and should continue to meet these till the award of the contract.

- 1.1. Valid manufacturing license/Factory License (Self–attested Copy) along with the list of products manufactured in this facility wherever applicable. The quoted products should be highlighted for ready reference.
- 1.2. All Pharmaceutical products should have relevant & valid WHO GMP certificate and COPP (Certificate of Pharmaceutical Product).
- 1.3. Original Manufacturers having a minimum average annual turnover of Rs.1 Crore (Rupees One Crore only) during the last three years i.e., 2021-2022, 2022-2023 and 2023-2024 (original/ provisional) will only be eligible for participation.

Authorized agents are also eligible to bid provided their minimum average turnover in the last three years i.e., 2021-2022, 2022-2023 and 2023-2024 (original/ provisional) is Rs.50 lakh (Rupees Fifty lakhs only) and their Principal manufacturers meets the eligibility criteria for principal manufacturer as specified above.

In case of bid by authorized agents, manufacturers authorization form must be attached with the bid submitted. If an Original Manufacture is participating in the tender but wishes to make the supplies through its authorised agent, the manufacturer has to ensure that the Authorised agent meets all the eligible criteria mentioned, including minimum average turnover in the last three years i.e., 2021-2022, 2022-2023 and 2023-2024 (original/ provisional) (original / provisional) is Rs.50 lakh (Rupees Fifty lakhs only) and documentary proof for the same has to be attached along with original authorization letter.





- 1.4. The offered supply should comply with the provisions of the relevant standards for the product as applicable as amended up to date.
- 1.5. The Bidder must submit an in-house batch wise COA pass test report (hard copy), manufacturing license with product permission, WHO GMP certificate and COPP certificate for every batch of items along with consignment, Real time stability data and soft copies of COA's shall be send to sdrbdsouth@lifecarehll.com.
- 1.6. The bidder should submit MSDS certificate for all dangerous goods & all necessary documents as specified against each item in the technical specification along with the consignment, if asked
- 1.7. Firm should submit a non-conviction certificate issued by the State Drug Controller, to the effect that the manufacturer has not been convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the preceding three years and that no case / proceedings is pending against the manufacturer in any Court of Law in India under the Drugs & Cosmetics Act and for Non-Pharma items self-declared non conviction from bidder/manufacture to be submitted.
- 1.8. Primary manufacturers/authorized agents are allowed to participate in the Tender. Manufacturer's authorization form in original may be submitted by participating authorized agents.
- 1.9. The bidders who are able to supply the items within 7 days from the date of PO are only eligible to bid.
- 1.10. Suppliers must ensure strict compliance to all statutory regulations, quality standards and Packing material specifications (as applicable) detailed in Annexure 5.
- 1.11. A firm/bidder shall submit only one bid in the same bidding process. A Bidder (either as a firm or as an individual or as a partner of a firm) who submits or participates in more than one bid will cause all the proposals in which the Bidder has participated to be disqualified.
- 1.12. Bidders who are eligible as per the Provisions of Public Procurement –Preference to Make in India Order No.P-45021/12/2017PP (BE-II), 2017 (published by Department for Promotion of Industry and Internal Trade) inclusive of the latest amendments are eligible to participate in the tender. A self-declaration as per Annexure 14 with respect to this order must be submitted.
- 1.13. Any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with Competent Authority, as per order no F.No.6/18/2019-PPD dated 23-July-2020 (Rule 144 (xi) of the GFR, 2017 and any amendments issued thereafter) inclusive of the latest amendments issued by Ministry of Finance, GOI at Annexure 13 of this bidding document. The bidder must comply with all provisions mentioned in this order. A self-declaration as per Annexure 13 with respect to this order must be submitted.
- 1.14. Purchase preference to Micro and Small Enterprises (MSEs): Purchase preference will be given to MSEs as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent Orders/Notifications issued by concerned Ministry.
- 1.15. (a) Bidder/ manufacturer who has been de-recognized/debarred/banned/blacklisted for the product mentioned in the tender by any other State Government / Central Govt. Organization /State Medical Corporations/ Director Health Services and or convicted by any court of law due to (i) quality failure of the drug(s) supplied (NSQ/ Spurious/ Adulterated/ Misbranded etc.) (ii) Submission of fake or forged documents (iii) Submission of incorrect information / Suppression of vital information & facts can't





participate for that product in the tender during the period of de-recognition / debarment/ Banned/blacklisted. Bidder / manufacturing unit which has been derecognized/ debarred/banned/blacklisted by State Medical Corporation for any reasons can't participate for that product in the tender during the period of derecognition/debarment/banned. If we, at a later date, are found guilty of suppressing facts in this regard, such act on our part shall be considered a fraudulent practice in accordance with the Instructions to Bidders and the Purchaser shall be entitled to reject our BID for the product quoted, submitted by us against this Tender.

(b) Any bidder who has been convicted by a competent court of law for supplying (NSQ/ Spurious/ Adulterated/ Misbranded etc.) drugs within a period of last 3 years from the date of floating of tender shall not be eligible to participate in the tender for that product.

(c) Any bidder who is a distributor/ authorized agent then they should ensure that their Principal manufacturer is not been de-recognized/debarred/banned/blacklisted for the quoted product by any other State Government / Central Govt. Organization /State Medical Corporations/ Director Health Services and or convicted by any court of law due to (i) quality failure of the drug(s) supplied (NSQ/ Spurious/ Adulterated/ Misbranded etc.) (ii) Submission of fake or forged documents (iii) Submission of incorrect information / Suppression of vital information & facts can't participate for that product in the tender during the period of de-recognition / debarment/ Banned/blacklisted. Bidder / manufacturing unit which has been de-recognized/ debarred/banned/blacklisted by State Medical Corporation for any reasons can't participate for that product in the tender during the tender during the period of de-recognition/debarment/banned. If we, at a later date, are found guilty of suppressing facts in this regard, such act on our part shall be considered a fraudulent practice in accordance with the Instructions to Bidders and the Purchaser shall be entitled to reject our BID for the product quoted, submitted by us against this Tender.

- 1.15. The products offered in the tender must be only manufactured in INDIA
- 1.16. For the Items quoted in the tender enquiry, firm will have to submit the samples on demand. If firm fails to submit the samples, the tender will be rejected.
- 1.17. MRP should not be printed on any package.

1.18 All the cold chain items to be transported to HLL warehouse with Data Logger for Cold Chain Maintenance

Clause No.07

7.2 Documents to be submitted along with the Technical Bid

The online bid submitted by the bidder shall comprise the following:

- a) Self-Declaration as per Annexure 1
- b) Bid form as per Annexure-2
- c) Valid manufacturing license/Factory License/Drug License issued by state drug controller (Self-attested Copy) along with the list of products manufactured in this facility wherever applicable. The quoted products should be highlighted for ready reference.
- d) All Pharmaceutical products should have relevant & valid WHO GMP certificate.
- e) All pharmaceutical products should have valid COPP (Certificate of Pharmaceutical Product).
- f) Should submit relevant document for all the quoted items complying with BP/USP/IP standards specified in Annexure 4 technical specifications.





- g) Firm should submit a non-conviction certificate issued by the State Drug Controller to the effect that the manufacturer has not been convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the preceding three years and that no case / proceedings is pending against the manufacturer in any Court of Law in India under the Drugs & Cosmetics Act.
- h) Power of attorney for signatory of bid in Rs 200/- stamp paper duly notarized.
- i) Copy of GST Certificate (self-attested copy)
- j) Copy of Permanent Account Number (Self-attested Copy)
- k) Certificate of incorporation and associated documents like Article of Association and Memorandum of Association/Partnership deed/HUF etc as applicable. (Self-attested Copy).
- I) Under taking letter for replacement of complaint/defective goods as per Annexure-3
- m) List of quoted products with specification Compliance- Annexure 4
- n) Suppliers must ensure strict compliance to all statutory regulations, quality standards and packing material specifications (as applicable) detailed in Annexure 5
- o) Authorization letter from manufacturer (Original) must be submitted as per Annexure 6.
- p) Documentary proof attested by Charted Accountant for establishing the average annual turnover of Original Manufacturers having a minimum average annual turnover of Rs.1 Crore (Rupees One Crore only) during the last three years i.e. 2021-2022, 2022-2023 and 2023-2024 (original/ provisional). In case of Authorized agents they must submit the documentary proof for minimum average turnover in the last three years i.e., 2021-2022, 2022-2023 and 2023-2024 (original/ provisional) is Rs.50 lakhs (Rupees Fifty lakhs only) and documentary proof attested by Charted Accountant for establishing their Principal manufacturers meets the eligibility criteria for original manufacturer as specified above. In case of bid by authorized agents, manufacturers authorization form must be attached with the bid submitted.

If an Original Manufacture is participating in the tender but wishes to make the supplies through its authorised agent, the manufacturer has to ensure that the Authorised minimum average turnover in the last three years i.e., 2021-2022, 2022-2023 and 2023-2024 (original/ provisional) is Rs.50 lakhs (Rupees Fifty lakhs only) and documentary proof attested by Charted Accountant for the same has to be attached.

- q) Annexure 7 Category details of organization, in case of MSE, If the bidder is a MSE, it shall declare in the bid document the Udyog Aadhar Memorandum Number issued to it under the MSMED Act, 2006. If a MSE bidder do not furnish the UAM Number along with bid documents, such MSE unit will not be eligible for the benefits available under Public Procurement Policy for MSEs Order 2012."
- r) Duly filled, signed and sealed Annexure 8 Indemnity Certificate
- s) Annexure 10 Check List
- t) Annexure 11 Compliance To Rule 144 (XI) of GFR 2017 (Self Declaration)
- u) Annexure 12 Make In India Preference (Self Declaration)
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- x) Annexure 15- Bidder Info
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- z) Annexure 17- Indicative Challan





aa) The bidder should submit label and Product information leaflet for the quoted products.

Note: If any of the above document are not applicable for eligible bidders then they shall attach a "NOT APPLICABLE "statement mentioning the justification for the same. All Annexures must be dully signed and sealed while submitting the same.

Bidders shall not make any addition, deletion or correction in any of the bid documents. If tampering of documents is noticed during tender evaluation, the bid will be rejected and the bidder will be blacklisted.

MAY BE READ AS

1. <u>Section 1</u> Clause No.03; <u>TECHNICAL SPECIFICATION</u> All Pharmaceutical products should have relevant & valid WHO GMP certificate, COPP (Certificate of Pharmaceutical Product) or Country Registration certificate (Sri Lanka).

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- aa) The bidder should submit label and Product information leaflet for the quoted products.

Note: If any of the above document are not applicable for eligible bidders then they shall attach a "NOT APPLICABLE "statement mentioning the justification for the same.

All Annexures must be dully signed and sealed while submitting the same.

Bidders shall not make any addition, deletion or correction in any of the bid documents. If tampering of documents is noticed during tender evaluation, the bid will be rejected and the bidder will be blacklisted.

All relevant clauses of the **tender document including price sheet** are to be read in accordance with the above change and in case if any bids were already submitted, you may resubmit the documents in compliance of the above amendment. All other specifications, terms and conditions of the original tender document shall remain unchanged.

Vice President (PS) & GH (HCS)